

**IN THE UNITED STATES DISTRICT COURT FOR  
THE WESTERN DISTRICT OF VIRGINIA  
ROANOKE DIVISION**

**SHARON G. WINGATE,  
EXECUTOR OF THE ESTATE OF  
DOUGLAS GRAY WINGATE, DECEASED**

**Plaintiff,**

**V.**

**Case No.:** 7:13CV00142

**INSIGHT HEALTH CORP.,  
JOHN MATHIS, M.D.,  
ROBERT F. O'BRIEN, M.D.,  
And  
IMAGE GUIDED PAIN MANAGEMENT,  
P.C.**

## Defendants.

## NOTICE OF REMOVAL

Defendant INSIGHT HEALTH CORP., hereinafter (“IHC”), by and through counsel, Bonner Kiernan Trebach & Crociata, LLP, and pursuant to 28 U.S.C. 1334, 1446(b)(3) and 1452, hereby removes the above-captioned matter from the Circuit Court for the City of Roanoke, Virginia to this Court. The grounds for removal are set forth below.

### **Nature of the Claims and Procedural History**

1. This case is related to one of many lawsuits filed around the country that involves persons who were injured after receiving an injection with contaminated steroids that were manufactured and sold by the New England Compounding Center a/k/a New England Compounding Pharmacy (“NECC”).

2. On or about December 27, 2012, Plaintiff Sharon G. Wingate, Executor of the Estate of Douglas Gray Wingate, deceased, hereinafter (“Plaintiff Wingate”) filed an action in the Circuit

Court for the City of Roanoke, Virginia, styled *Sharon G. Wingate, Executor of the Estate of Douglas Gray Wingate, Deceased v. Insight Health Corp., John Mathis, M.D., Robert F. O'Brien, M.D., and Image Guided Pain Management, P.C.*, asserting claims of negligence, negligence *per se*, violation of the Virginia Consumer Protection Act, and fraud, against IHC and the other defendants, following Douglas Wingate's death stemming from a contaminated steroid manufactured and provided by NECC. (In accordance with 28 U.S.C. §1446(a), true and correct copies of the Complaint, Summons, and related court filings are attached hereto, as Exhibit A.) The Complaint did not, however, name NECC as a defendant.

3. Before filing her suit against IHC, on or about November 20, 2012, Plaintiff Wingate filed a separate action in this Court solely against NECC ("WDVA NECC Action"). (A copy of the Complaint against NECC in the WDVA NECC Action is attached as Exhibit B).

4. On December 21, 2012, NECC filed for Chapter 11 bankruptcy protection in the United States Bankruptcy Court for the District of Massachusetts. Thereafter, NECC filed a suggestion of bankruptcy in the WDVA NECC Action, effectively staying that action with plaintiff Wingate. (A copy of the Suggestion of Bankruptcy filed by NECC is attached as Exhibit C). Plaintiff Wingate has since filed a proof of claim as a tort creditor in the NECC bankruptcy case.

5. Plaintiff Wingate filed the state court action against IHC, Image Guided Pain Management, P.C and Drs. Mathis and O'Brien *after* the WDVA NECC Action was effectively stayed.

6. Because NECC was not a party to Plaintiff Wingate's state court action, IHC filed a demurrer to her complaint asserting that the Complaint was defective because, *inter alia*, she failed to name a necessary and indispensable party, *i.e.*, NECC. Accordingly, without NECC as

a party to the state court action, complete relief could not be afforded among the parties. (A copy of IHC's Demurrer is attached as Exhibit D).

7. Defendant IGPM and Drs. Mathis and O'Brien (the "Local Defendants") filed a similar pleading asserting that NECC was a necessary and indispensable party, albeit under a different procedural motion, couched as a Plea In Bar. (A copy of the Local Defendants' Plea In Bar that NECC is a Necessary and Indispensable Party is attached as Exhibit E). However, on March 26, 2013, the Local Defendants withdrew this Plea in Bar which, unlike a demurrer, could be re-filed at a later date.

8. On February 28, 2013, the state court heard IHC's demurrer to dismiss Plaintiff Wingate's complaint. The state court, however, has not yet rendered a decision on the necessary and indispensable party issue related to NECC. IHC is not required to, nor has it yet, filed an answer to Plaintiff Wingate's complaint in the state court action until there is a decision on its demurrer.

9. Around the same time, a Multidistrict Litigation Panel was established for all matters across the country involving NECC, including the WDVA NECC Action and a separate suit against IHC, *Mowles v. Insight Imaging Roanoke*, Case No. 7:13-cv-00016, that was pending in the Western District of Virginia, Roanoke Division. The Multidistrict Litigation Panel Case No. is MDL 2419, and has been established in the United States District Court for the District of Massachusetts. (A copy of the MDL Docket Sheet is attached as Exhibit F).

10. On March 10, 2013, the Chapter 11 Bankruptcy Trustee for the Estate of NECC filed a Motion to Transfer Personal Injury Tort and Wrongful Death Cases pursuant to 28 U.S.C. §§ 157(b)(5) and 1334 to the MDL in order to transfer and consolidate all cases in which NECC is

named as a defendant and/or in all cases that are “related to” the NECC bankruptcy in the MDL. (A copy of the Trustee’s Motion to Transfer is attached as Exhibit G).

11. As a result, the state court action became removable under 28 U.S.C §1446 (b)(3) as of March 10, 2013, when the Trustee declared that all such matters are related to the NECC bankruptcy, which constituted such “other paper from which it may first be ascertained that the case is one which is or has become removable.” (*Id.*)

12. IHC timely files this Notice of Removal as it is within 30 days of March 10, 2013, the date upon which this case became removable. 28 U.S.C. §1446 (b)(3).

13. The time period in which to file a proof of claim in the NECC Bankruptcy remains open, and IHC intends to file its proof of claim against NECC in the coming days. Moreover, there has been no plan confirmation in the bankruptcy matter.

14. Last, after learning of the Chapter 11 Trustee’s Motion to Transfer, the Local Defendants withdrew their motion to argue their previously filed Plea in Bar seeking the state court’s ruling that NECC is a necessary and indispensable party to the state court action. Under the procedural Rules of the Supreme Court of Virginia, unlike the timing involved in filing a demurrer, a plea in bar need not be filed at the responsive pleading stage.

### **PARTIES**

15. Plaintiff Wingate is a citizen of the Commonwealth of Virginia.

16. At the time Plaintiff commenced the action against IHC, IHC was and remains a corporation incorporated under the laws of the State of Delaware, having its principal place of business located in the State of Minnesota.

17. The Local Defendants are, upon information and belief, citizens of, and a corporation incorporated under the laws of the Commonwealth of Virginia.

### **GROUND FOR REMOVAL**

18. Removal is appropriate here under 28 U.S.C. § 1452 because this court has original jurisdiction under 28 U.S.C. § 1334(b), as the instant suit is related to the NECC Bankruptcy case. Under 28 U.S.C. § 1452(a) “a party may remove any claim ... in a civil action ... to the district court for the district where such civil action is pending, if such district court has jurisdiction of such claim or cause of action under Section 1334.” Under 28 U.S.C. § 1334(b), “... the district courts shall have original but not exclusive jurisdiction of all civil proceedings arising under Title 11, or arising in or ‘related to’ cases under Title 11.” The test for determining whether a civil proceeding is “related to” bankruptcy is “whether the outcome of that proceeding could *conceivably have any effect* on the estate being administered in the bankruptcy.” *See A.H. Robins Co. v. Piccinin*, 788 F.2d 994, 1002 (4th Cir. 1986) (citing *Pacor, Inc. v. Higgins*, 743 F.2d 984, 994 (3rd Cir. 1984) (emphasis added)).<sup>1</sup> Thus, “[a]n action is related to bankruptcy if the outcome could alter the debtor’s rights, liabilities, options or freedom of action (either positively or negatively) and [it] in any way impacts upon the handling of the administration of the bankruptcy estate.” *Valley Historic Ltd. P’ship v. The Bank of New York*, 486 F.3d 831, 836 (4th Cir. 2007) (citations omitted).

19. Plaintiff Wingate’s complaint against IHC includes more than 45 paragraphs devoted to NECC’s operations and tortious misfeasance which are at the core of Plaintiff’s claims against IHC in the subject state court action. (*See Complaint at Exhibit A*). Further, IHC would have,

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<sup>1</sup> Although the Supreme Court of the United States had overturned *Pacor* in part on other grounds, it has not disturbed the “related to” test enunciated in *Pacor*.

among other things, direct claims against NECC, including, but not limited to, claims under the Virginia Drug Control Act, as well as claims for contribution and indemnification. Accordingly, NECC's actions or omissions are also at the heart of Plaintiff Wingate's complaint against IHC, and any findings or rulings in the state court action, especially in the absence of NECC, would certainly "alter [NECC's] rights, liabilities, options or freedom of action" and would certainly "impact the administration of the NECC estate." Thus, Plaintiff Wingate's complaint unquestionably relates to NECC bankruptcy, providing this Court with original jurisdiction over the subject state court matter.

20. It is important to also note that, Plaintiff Wingate has already filed a proof of claim against NECC in the bankruptcy proceeding, subjecting herself to the jurisdiction of the bankruptcy court. IHC also intends to file a proof of claim before the time period in which to file such a claim closes. Therefore, the subject state court action has a close nexus to the bankruptcy proceedings and any reorganization plan that would be submitted by the debtor-NECC in the bankruptcy. Indeed, the Chapter 11 Trustee has already made such a determination through its Motion to Transfer that this action is related to the bankruptcy action and has specifically indentified this case (and other related cases in the Circuit Court for the City of Roanoke involving IHC) as one over which the federal district courts would have original jurisdiction and that this case should be removed and transferred. (*See Exhibit G*). Accordingly, Plaintiff Wingate's state court action is "related to" the NECC bankruptcy, and this Court has original jurisdiction over the matter. (*See* 28 U.S.C. § 1334(b)).

21. In addition, Plaintiff Wingate did not file her complaint against IHC until *after* NECC had already filed for bankruptcy protection. As a result, any of IHC's claims against NECC would have not have been ripe until after the filing of plaintiff Wingate's post-petition

complaint. Thus, because any claims on the part of IHC against NECC are post-petition, any such claims would also necessarily “arise under” Title 11. 28 U.S.C. §1334 (b); *see also Valley Historic*, 486 F.3d at 836 (noting that while causation is not a sufficient basis on which to confer arising in jurisdiction, a claim may arise under Title 11 for the purposes of 1334 where “...the very purpose of bankruptcy is to discharge and restructure the debt that has caused the bankruptcy.”) Here, the sole basis for NECC’s filing for bankruptcy protection is due to its liability stemming for the contaminated steroids that it manufactured and distributed around the country. It therefore follows that IHC’s claims against NECC, which are due to NECC’s actions, inactions or omissions, are at the center of the bankruptcy.

22. Without NECC a party to the state court action, and due to NECC’s bankruptcy, IHC cannot adequately defend itself because, among other things, IHC cannot to obtain critical discovery from NECC as to plaintiff’s allegations that, for instance, IHC “knew or should have known” that NECC was capable of manufacturing and selling contaminated drugs to them for use on their patients. (*See Exhibit A*, Counts I, III, and IV of Negligence, Negligence *Per Se*, and Gross Negligence of the Complaint). Yet NECC cannot be brought into the state court matter due to its bankruptcy filing.

23. Pursuant to 28 U.S.C. §1446(d), a copy of this Notice of Removal is being filed with the Clerk of the Circuit Court for the City of Roanoke, Virginia. IHC also will promptly serve a copy of this Notice on counsel for plaintiff and (to the extent they have entered an appearance or are otherwise known) counsel for other parties to the removed case. (A copy of the Notice to the Clerk of Removal is attached as Exhibit H).

24. No admission of law, fact, or liability is intended by this Notice of Removal, and all defenses and motions are reserved to the Removing Defendant.

WHEREFORE, Defendant Insight Health Corp. hereby removes the above captioned case, which is now pending in the Circuit Court of Virginia for the City of Roanoke, to the United States District Court for the Western District of Virginia, Roanoke Division.

Date: April 4, 2013

**BONNER KIERNAN TREBACH & CROCIATA,  
LLP**

/s/Christopher E. Hassell  
Christopher E. Hassell, Esquire VSB#30469  
Clinton R. Shaw, Jr. VSB#37498  
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*Counsel for Insight Health Corp.*

Of Counsel:

Brian J. Gerling, Esquire  
VSB#75817  
1233 20<sup>th</sup> Street, N.W., Suite 800  
Washington, D.C. 20036



**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY, that I caused to be served the foregoing Notice of Removal

INSIGHT HEALTH CORP. via U.S. Mail postage prepaid 4th day of April, 2013 to:

J. Scott Sexton  
Gentry Locke Rakes & Moore, LLP  
10 Franklin Road, S.E., Suite 800  
P.O. Box 40013  
Roanoke, Virginia 24022-0013  
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f540.983.9400  
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**BONNER KIERNAN TREBACH & CROCIATA,  
LLP**

/s/Christopher E. Hassell  
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*Counsel for Insight Health Corp.*

## COMMONWEALTH OF VIRGINIA



### ROANOKE CITY CIRCUIT COURT

Civil Division  
315 CHURCH AVENUE, SW  
ROANOKE VA 24016  
(540) 853-6702

Virginia:

Proof of Service

In the ROANOKE CITY CIRCUIT COURT

Case number: 770CL12002547-00

Service number: 001

Service filed: December 27, 2012

Judge:

Served by: HENRICO COUNTY

Style of case: SHARON G WINGATE EXOR vs INSIGHT HEALTH CORP

Service on: INSIGHT HEALTH CORP  
CT CORPORATION SYSTEM  
ITS REGISTERED AGENT  
4701 COX ROAD  
SUITE 301  
GLEN ALLEN VA 23060

Attorney: SEXTON, J SCOTT; ESQ  
540-983-9300

### Instructions:

Returns shall be made hereon, showing service of Summons issued Friday, December 28, 2012 with a copy of the Complaint with Interrogatories and Production of Documents filed Thursday, December 27, 2012 attached.

Hearing date :

Service issued: Friday, December 28, 2012

For Sheriff Use Only

EXHIBIT

A

**COMMONWEALTH OF VIRGINIA**



**ROANOKE CITY CIRCUIT COURT**

**Civil Division**

**315 CHURCH AVENUE, SW**

**ROANOKE VA 24016**

**(540) 853-6702**

**Summons**

**To: INSIGHT HEALTH CORP  
CT CORPORATION SYSTEM  
ITS REGISTERED AGENT  
4701 COX ROAD  
SUITE 301  
GLEN ALLEN VA 23060**

**Case No. 770CL12002547-00**

The party upon whom this summons and the attached complaint are served is hereby notified that unless within 21 days after such service, response is made by filing in the clerk's office of this court a pleading in writing, in proper legal form, the allegations and charges may be taken as admitted and the court may enter an order, judgment, or decree against such party either by default or after hearing evidence.

Appearance in person is not required by this summons.

Done in the name of the Commonwealth of Virginia on, Friday, December 28, 2012

Clerk of Court: BRENDA S. HAMILTON

by Wanda H. Hildress  
(CLERK/DEPUTY CLERK )

Instructions:

Hearing Official:

Attorney's name: **SEXTON, J SCOTT; ESQ**  
**540-983-9300**

**CIRCUIT COURT**  
Received & Filed  
1:42 PM  
DEC 27 2012  
By [Signature]  
Deputy Clerk  
CITY OF ROANOKE

**VIRGINIA:**

**IN THE CIRCUIT COURT FOR THE CITY OF ROANOKE**

**SHARON G. WINGATE,  
EXECUTOR OF THE ESTATE OF  
DOUGLAS GRAY WINGATE,  
DECEASED,**

*Plaintiff,*

**v.**

**INSIGHT HEALTH CORP.,  
CT Corporation System, Its Registered Agent  
4701 Cox Road, Suite 301  
Glen Allen, Virginia 23060  
(Henrico County)**

**JOHN M. MATHIS, M.D.,  
2923 Franklin Rd., S.W.  
Roanoke, Virginia 24014  
(Roanoke City)**

**ROBERT F. O'BRIEN, M.D.,  
2923 Franklin Rd., S.W.  
Roanoke, Virginia 24014  
(Roanoke City)**

**AND**

**IMAGE GUIDED PAIN MANAGEMENT,  
P.C.,  
Heman A. Marshall, Esq., Its Registered Agent  
Woods Rogers, PLC  
Wells Fargo Tower, 14<sup>th</sup> Floor  
Roanoke, Virginia 24011  
(Roanoke City)**

*Defendants.*

Case No:

CL12-2547

**COMPLAINT**

COMES NOW Sharon G. Wingate, Executor of the Estate of Douglas Gray Wingate, deceased, by counsel, and files this Complaint against the Defendants and states as follows:

## PARTIES

1. On September 18, 2012, Douglas Gray Wingate ("Mr. Wingate") died as a result of brain damage and other complications caused by fungal meningitis as a result of the epidural steroid injection which is at issue in this case.

2. On October 5, 2012 in the Commonwealth of Virginia Mr. Wingate's wife, Sharon G. Wingate ("Mrs. Wingate") duly qualified as the Executor of Mr. Wingate's Estate.

3. Mr. Wingate was a citizen of the Commonwealth of Virginia.

4. Mrs. Wingate is a citizen of the Commonwealth of Virginia.

5. Insight Imaging-Roanoke is located at 2923 Franklin Road, S.W. Roanoke, Virginia 24014.

6. Insight Imaging-Roanoke is a registered fictitious name of Image Guided Pain Management, P.C. ("Image Guided").

7. Insight Health Corp. ("Insight Health") transacts business in the Commonwealth of Virginia under the fictitious name of Insight Imaging-Roanoke.

8. Insight Health has not registered the fictitious name of Insight Imaging-Roanoke in violation of Virginia Code §§ 59.1-69 and 59.1-70.

9. At all times and places pertinent to this action, Insight Health transacted business in the Commonwealth of Virginia under the fictitious name of Insight Imaging-Roanoke.

10. At all times and places pertinent to this action, Insight Health owned, operated and controlled Insight Imaging-Roanoke.

11. Unless otherwise specified in this Complaint, references to Insight Imaging-Roanoke include Image Guided and Insight Health.

12. At all times and places pertinent to this action, Insight Health made the actual decisions and arrangements relating to the selection, procurement, and preparation of drugs administered at Insight Imaging-Roanoke, including the epidural steroid drug which is at issue in this case.

13. Insight Health is incorporated in the State of Delaware.

14. Insight Health's principal place of business is in the State of California.

15. At all times and places pertinent to this action, Insight Health advertised to the public that it was a national provider of diagnostic imaging services.

16. At all times and places pertinent to this action, Insight Health advertised to the public that it was committed to providing the best imaging experience possible, and it called this "Patients First care".

17. At all times and places pertinent to this action, Insight Health advertised to the public that one of its core values was to "do the right thing".

18. At all times and places pertinent to this action, Insight Health advertised to the public that one of its core values was integrity.

19. At all times and places pertinent to this action, Insight Health advertised to the public that one of its core values was ethics.

20. At all times and places pertinent to this action, Insight Health advertised to the public that one of its core values of doing the right thing, integrity, and ethics took priority over profits.

21. At all times and places pertinent to this action, Insight Health advertised to the public that one of its core values of doing the right thing, integrity, and ethics took priority over expediency.

22. At all times and places pertinent to this action, Insight Health advertised to the public that it offered the highest quality of care through a network of outpatient imaging centers and mobile facilities.

23. At all times and places pertinent to this action, Insight Health advertised to the public that one of its centers was Insight Imaging-Roanoke, located at 2923 Franklin Road, S.W. Roanoke, Virginia 24014.

24. At all times and places pertinent to this action, Insight Health advertised to the public that one of the modalities that it provided at Insight Imaging-Roanoke was pain management image-guided therapeutics.

25. Insight Health procured, received, and provided to Mr. Wingate the epidural steroid injection which is at issue in this case.

26. Dr. John M. Mathis ("Dr. Mathis") is a citizen of the Commonwealth of Virginia.

27. At all times and places pertinent to this action, Insight Imaging-Roanoke allegedly designated Dr. Mathis as its medical director.

28. At all times and places pertinent to this action, Insight Imaging-Roanoke allegedly held Dr. Mathis out to the public as its medical director.

29. On information and belief, Dr. Mathis would allege that Insight Imaging-Roanoke designated him as its medical director without his permission or consent.

30. On information and belief, Dr. Mathis would allege that Insight Imaging-Roanoke held him out to the public as its medical director without his permission or consent.

31. On information and belief, Dr. Mathis would allege that Insight Imaging-Roanoke never asked him to be its medical director.

32. On information and belief, Dr. Mathis would allege that he never gave his permission or consent to be Insight Imaging-Roanoke's medical director.

33. On information and belief, Dr. Mathis would allege that he was never compensated to be Insight Imaging-Roanoke's medical director.

34. On information and belief, Dr. Mathis would allege that he never acted as Insight Imaging-Roanoke's medical director.

35. If Dr. Mathis agreed to be or acted as the medical director of Insight Imaging-Roanoke during the times and places pertinent to this action, then he was ultimately responsible for Insight Imaging-Roanoke's choices regarding the procurement of drugs, such as Mr. Wingate's epidural steroid drug which is at issue in this case.

36. If Dr. Mathis did not agree to be or act as the medical director of Insight Imaging-Roanoke during the times and places pertinent to this action, then Insight Imaging-Roanoke falsely designated and held out Dr. Mathis to the public as its medical director, and Insight Health delegated to non-medical staff the important patient care function of choosing safe and effective drugs for its patients.

37. At all times and places pertinent to this action, Dr. Mathis was an employee and/or agent of Insight Imaging-Roanoke acting in the course and scope of his employment or agency.

38. At all times and places pertinent to this action, Insight Imaging-Roanoke acted through its employees and agents including, but not limited to, Dr. Mathis.

39. At all times and places pertinent to this action, Insight Imaging-Roanoke was vicariously liable for Dr. Mathis' actions and omissions.



40. Dr. Robert F. O'Brien ("Dr. O'Brien") is a citizen of the Commonwealth of Virginia.

41. Dr. O'Brien performed Mr. Wingate's epidural steroid injection at Insight Imaging-Roanoke.

42. At all times and places pertinent to this action, Dr. O'Brien was an employee and/or agent of Insight Imaging-Roanoke acting in the course and scope of his employment or agency.

43. At all times and places pertinent to this action, Insight Imaging-Roanoke acted through its employees and agents including, but not limited to, Dr. O'Brien.

44. At the times and places pertinent to this action, Insight Imaging-Roanoke was vicariously liable for Dr. O'Brien's actions and omissions.

45. At all times and places pertinent to this action, Insight Imaging-Roanoke also did business through other employees and agents located in Roanoke and other places in the United States including, but not limited to, Paul Hellkamp, secretaries, nurses, technicians, staff, and personnel.

46. At the times and places pertinent to this action, Insight Imaging-Roanoke was vicariously liable for the actions and omissions of its other employees and agents located in Roanoke and other places in the United States including, but not limited to, Paul Hellkamp, secretaries, nurses, technicians, staff, and personnel.

47. Image Guided is incorporated in the Commonwealth of Virginia.

48. Image Guided's principal place of business is in the City of Roanoke, Virginia.

#### JURISDICTION AND VENUE

49. Subject matter jurisdiction is proper pursuant to Virginia Code § 17.1-513.

50. Personal jurisdiction over Insight Health is proper pursuant to at least Virginia Code §§ 8.01-328.1(A)(1), (2), (3), (4) & (6).

51. Personal jurisdiction over Image Guided, Dr. Mathis, and Dr. O'Brien is proper pursuant to at least Virginia Code §§ 8.01-328.1(A)(1), (2), (3) & (6).

52. Venue is proper pursuant to Virginia Code §§ 8.01-262(1) & (2).

### FACTS

53. At all times and places pertinent to this action, Insight Imaging-Roanoke and its employees and agents had a healthcare provider-patient relationship with Mr. Wingate.

54. Insight Imaging-Roanoke and its employees and agents owed Mr. Wingate numerous duties including, without limitation, the following: to act as reasonable and prudent healthcare providers; to provide the best imaging experience possible; to act ethically; to act with integrity; to do the right thing; to place patient care first; to place ethics, integrity, doing the right thing, and patient care above profits; and to ensure that the drugs that they gave to patients were safe and effective.

55. At all times and places pertinent to this action, Mr. Wingate relied upon the advice and treatment provided by Insight Imaging-Roanoke and its employees and agents, which had specialized training and superior knowledge regarding treatment, use of drugs, and the source of drugs.

56. Insight Imaging-Roanoke and its employees and agents intended to and in fact did use methylprednisolone acetate in epidural steroid injections, including the injection provided to Mr. Wingate which is at issue in this case.

57. The use of methylprednisolone acetate in epidural steroid injections by Insight Imaging-Roanoke and its employees and agents has never been approved by the Food and Drug Administration (“FDA”).

58. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that the use of methylprednisolone acetate in epidural steroid injections has never been approved by the FDA.

59. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that use of methylprednisolone acetate in epidural steroid injections is an off-label use.

60. Insight Imaging-Roanoke and its employees and agents knew, or should have known, the importance of purchasing safe and effective drugs for their patients and this importance was greatly heightened by the fact that the use of methylprednisolone acetate in epidural steroid injections has never been approved by the FDA.

61. Insight Imaging-Roanoke and its employees and agents knew, or should have known, the danger to which their patients would be exposed if they purchased unsafe and/or ineffective drugs for its patients.

62. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that the best way of ensuring safe and effective drugs for their patients was to purchase such drugs from an FDA-regulated manufacturer or an accredited pharmacy that complied with all federal and state laws.

63. Insight Imaging-Roanoke and its employees and agents assumed the responsibility for purchasing safe and effective drugs for its patients, including Mr. Wingate.

64. Insight Imaging-Roanoke and its employees and agents assumed the responsibility for verifying that the pharmacy from which they purchased drugs was safe, reliable, accredited and in compliance with all federal and state laws.

65. New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC") was a compounding pharmacy located in Framingham, Massachusetts.

66. Compounding pharmacies are generally small operations that engage in mixing (or "compounding") drug products for specific patients, pursuant to a valid prescription.

67. Because they typically compound drug products in forms that are not commercially available, compounding pharmacies are not regulated by the FDA.

68. Rather, compounding pharmacies are generally regulated under state law applicable to pharmacies and pharmacists.

69. Although NECC operated in Massachusetts, it was also required to comply with Virginia law in order to fill prescriptions in Virginia.

70. NECC was required to be licensed and registered with the Virginia Board of Pharmacy.

71. Methylprednisolone acetate is a knock-off of the brand name drug, Depo-Medrol, which is manufactured by the FDA-regulated company, Pharmacia & Upjohn Company, a Division of Pfizer, Inc. ("Pfizer").

72. Other FDA-regulated drug manufacturers produce sterile generic versions of methylprednisolone acetate (with and without preservatives) in facilities that are also regulated, controlled, and inspected by the FDA.

73. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that sterile methylprednisolone acetate (with and without preservatives) may be purchased in generic from FDA-regulated drug manufacturers in the United States.

74. Rather than producing small quantities of this knock-off Depo-Medrol, NECC engaged in the very risky process of producing and marketing vast batches of this drug, thousands at a time.

75. NECC did so through a process of taking non-sterile ingredients and placing them into an aqueous mixture that then had to be rendered sterile.

76. Even without the large batches, NECC's process made the methylprednisolone acetate a high risk compound.

77. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC engaged in the process of producing and marketing vast batches of this drug.

78. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC's process made the methylprednisolone acetate a high risk compound.

79. NECC acted as a wholesale distributor by selling large quantities of methylprednisolone acetate.

80. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC acted as a wholesale distributor by selling large quantities of methylprednisolone acetate.

81. Under Virginia law, compounding pharmacists must ensure compliance with USP-NF standards (United States Pharmacopeial National Formulary). Virginia Code §54.1-3410.2(E).

82. NECC failed to comply with USP-NF standards.

83. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC was not compliant with USP-NF standards.

84. Moreover, pharmacists and pharmacies may not engage in “the regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products.” Virginia Code §54.1-3410.2(H)(2).

85. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC was producing enormous batches of commercially available methylprednisolone acetate, which NECC then sold in bulk.

86. Within just two months during the general time frame pertinent to this action, Insight Imaging-Roanoke alone purchased and injected over 600 doses of methylprednisolone acetate from NECC.

87. Such large-scale production of methylprednisolone acetate, a commercially available drug, is illegal under Virginia Code § 54.1-3410.2(H)(2).

88. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC’s large-scale production of methylprednisolone acetate and subsequent sale without individual prescriptions violated Virginia law.

89. NECC is not accredited by the Pharmacy Compounding Accreditation Board (“PCAB”) or any other similar organizations, such as The Joint Commission, that offer independent assurance as to the quality and competence of compounding pharmacies that meet certain requirements.

90. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC was not an accredited compounding pharmacy.

93. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that Massachusetts, the state in which NECC was located, had less stringent enforcement standards for compounding pharmacies than the Commonwealth of Virginia.

95. NECC produced methylprednisolone acetate without preservatives.

97. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that preservative free methylprednisolone acetate heightens the danger of the drug if it is not produced to the highest standards including a highly sterile environment.



98. Sterilization techniques, quality control measures, highly sterile environments and sterility testing are crucial to properly producing methylprednisolone acetate without preservatives.

99. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that sterilization techniques, quality control measures, highly sterile environments, and sterility testing were crucial to the methylprednisolone acetate that they were going to inject in its patients' spinal canals.

100. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC was an unaccredited compounding pharmacy producing a high-risk compound, starting with non-sterile components.

101. NECC's drug production operations took place in an aged building surrounded by a waste recycling center owned by one of the co-owners of NECC, Gregory Conigliaro.

102. NECC's drug production facility received many varieties of garbage and waste that were sorted, stored, and manipulated just outside the back door of the NECC facility.

103. These waste products include used mattresses, recycled on-site from sources such as hospitals, prisons, hotels, and dormitories.

104. A photograph of NECC's facility is attached as **Exhibit A**.

105. It is difficult to distinguish where NECC ends and the waste recycling center begins, if there is such a distinction in fact; but the waste facility lists its address as 701 Waverly Street, Framingham, Massachusetts while NECC lists its address as 697 Waverly Street.

106. The marketing company for NECC, however, lists its address as the same as the waste facility.



107. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC's drugs and production processes were unsanitary, unsterile, and lacked adequate quality control measures, and that NECC operated in a facility surrounded by a garbage and waste center.

108. Other image guided pain management clinics in the Roanoke area recognized NECC as a dangerous source of methylprednisolone acetate.

109. These other clinics chose to pay more to obtain methylprednisolone acetate from reliable sources, specifically rejecting the lower prices offered by NECC.

110. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC was a dangerous source of methylprednisolone acetate.

111. On information and belief, NECC charged Insight Imaging-Roanoke less for methylprednisolone acetate than did Pfizer, other FDA approved manufacturers of the generic, and other accredited or reliable compounding pharmacies.

112. At all times and places pertinent to this action, Insight Imaging-Roanoke was one of only two pain management clinics in the Commonwealth of Virginia that chose to purchase methylprednisolone acetate from NECC.

113. Under Virginia Code §54.1-3435.01(A), non-resident pharmacies that engage in wholesale distribution of prescription drugs into the Commonwealth of Virginia must register with and be licensed by the Virginia Board of Pharmacy, in addition to registering as a non-resident pharmacy.

114. NECC was registered in the Commonwealth of Virginia as a non-resident pharmacy, but it is not and was not registered as a wholesale distributor of prescription drugs as required by Virginia Code §54.1-3435.01(A).

115. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC was not registered to distribute prescription drugs wholesale in the Commonwealth of Virginia.

116. Insight Imaging-Roanoke and its employees and agents knew that the methylprednisolone acetate that they would purchase from a pharmacy would be injected directly into patients' spinal canals so as to enter the central nervous system.

117. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that the central nervous system is a relatively closed system, making treatment options more difficult in the event of an adulterated invasion.

118. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that the methylprednisolone acetate that they would purchase from a pharmacy acts as an immune system suppressing agent, thus weakening the patient's natural ability to fight off pathogens that could possibly be included in the injection.

119. Despite what Insight Imaging-Roanoke and its employees and agents knew, or should have known, concerning NECC, they chose to purchase methylprednisolone acetate from NECC, which was an unaccredited, sprawling compounding pharmacy that: (a) produced its drugs in the same complex as a waste facility; (b) produced the drugs in bulk batches (making mistakes more likely); (c) did not properly sterilize the drugs; (d) did not operate with adequate quality control measures; (e) did not operate in a sterile environment; (f) did not have adequately representative samples of the drugs independently tested by an FDA-approved testing facility before releasing them for distribution; (g) did not comply with USP-NF standards; and (h) violated several provisions of Virginia statutes designed to protect Virginia citizens from substandard and adulterated prescription drugs.

120. Despite what Insight Imaging-Roanoke and its employees and agents knew, or should have known, concerning NECC, they voluntarily purchased methylprednisolone acetate from NECC in order to inject it into their patients' spinal canals, including Mr. Wingate's spinal canal.

121. In addition, notwithstanding such knowledge, they voluntarily purchased methylprednisolone acetate wholesale from NECC without prescriptions.

122. On information and belief, Drs. Mathis and O'Brien would allege that this purchasing decision was made without their advice, consent, or knowledge.

123. On information and belief, Drs. Mathis and O'Brien would allege that at the times and places pertinent to this action they never knew that Insight Imaging-Roanoke and its employees and agents were purchasing the methylprednisolone acetate from NECC.

124. On information and belief, Drs. Mathis and O'Brien would allege that at the times and places pertinent to this action they never knew that the epidural steroid drug that they were injecting into patients' spinal canals, including Mr. Wingate's spinal canal, came from NECC.

125. On information and belief, Drs. Mathis and O'Brien would allege that they never would have used the methylprednisolone acetate from NECC, including with Mr. Wingate, if they had been informed that NECC was not an accredited compounding pharmacy.

126. On information and belief, Drs. Mathis and O'Brien would allege that they never would have used the methylprednisolone acetate from NECC, including with Mr. Wingate, if they had been informed that NECC did not comply with all federal and state laws.

127. On information and belief, Drs. Mathis and O'Brien would allege that they never would have used the methylprednisolone acetate from NECC, including with Mr. Wingate, if

they had been informed that it was being produced in a facility located beside a garbage and waste facility.

128. On information and belief, Drs. Mathis and O'Brien would allege that they never would have used the methylprednisolone acetate from NECC, including with Mr. Wingate, if they had been informed that it was being produced in a facility that did not comply with USP-NF standards.

129. On information and belief, Drs. Mathis and O'Brien would allege that the actions of Insight Imaging-Roanoke and its employees and agents deprived them from making informed and reasonable patient care decisions on behalf of their patients, including Mr. Wingate, concerning the information, and lack thereof, that they were provided concerning the epidural steroid drug.

130. In addition to Insight Imaging-Roanoke and its employees and agents apparently withholding information from Drs. Mathis and O'Brien, Insight Imaging-Roanoke and its employees and agents did not inform their patients, including Mr. Wingate, that they were receiving a knock-off drug produced from a compounding pharmacy, much less a compounding pharmacy with the characteristics and problems as described in the preceding paragraphs.

131. On the contrary, Insight Imaging-Roanoke and its employees and agents provided their patients, including Mr. Wingate, with invoices that falsely itemized the drug as "Depo-Medrol", the trademarked name brand drug manufactured by Pfizer.

132. The same invoices from Insight Imaging-Roanoke also falsely reference the National Drug Code, 0703-0051-01, (or an abbreviation of such code).

133. A redacted true and correct copy of this invoice is attached as **Exhibit B**.

134. Insight Imaging-Roanoke and its employees and agents also provided Mr. Wingate and other patients with literature indicating that the injection that they had received was Depo-Medrol, the trademarked name brand drug produced by Pfizer.

135. A representative copy of this literature is attached as **Exhibit C**.

136. Further, Insight Imaging-Roanoke and its employees and agents falsely coded methylprednisolone acetate on Mr. Wingate's medical and billing records using billing code J1040, the HCPCS code for the name brand drug produced by FDA-regulated Pfizer, as well as other FDA-regulated generic drug producers, such as Teva Parenteral Medicines, Inc., a/k/a SICOR Pharmaceuticals.

137. A compounded drug should not be billed with the J codes meant for commercially prepared, preservative free drugs.

138. Rather, the "unlisted" code, J3490, should be provided along with the name of the drug and the dosage administered.

139. Insight Imaging-Roanoke and its employees and agents falsely coded methylprednisolone acetate on Mr. Wingate's medical and billing records using the National Drug Code, 0703-0051-01, a unique product code that contains an FDA-assigned labeler code unique to the manufacturer of the drug.

140. Rather than disclosing that the methylprednisolone acetate injected into Mr. Wingate was a compounded drug from NECC, Insight Imaging-Roanoke and its employees and agents falsely used the unique NDC code assigned to the FDA-regulated drug manufacturer, Teva Parenteral Medicines, Inc., for single dose, 80 mg/mL, preservative free, methylprednisolone acetate.

141. A copy of a representative label for the Teva Parenteral drug is attached for reference as **Exhibit D**.

142. However, Teva Parenteral Medicines, Inc., a leading generic drug manufacturer, had nothing to do with the epidural steroid injection that was provided to Mr. Wingate.

143. Any reference in the records from Insight Imaging-Roanoke and its employees and agents to this Teva national drug code is simply false and completely misleading.

144. Similarly, Dr. O'Brien's medical documentation states that the drug injected into Mr. Wingate's spinal canal was "Depo-Medrol", the name brand drug produced by Pfizer.

145. On information and belief, Dr. O'Brien would allege that he referenced "Depo-Medrol" to indicate the name brand drug produced by Pfizer or a drug produced to the same high quality standards.

146. Mr. Wingate never received Depo-Medrol or a drug produced to the same high quality standards from Insight Imaging-Roanoke and its employees and agents.

147. A true and correct copy of Dr. O'Brien's report is attached as **Exhibit E**.

148. This report was provided to Mr. Wingate's primary care physician who was serving as Mr. Wingate's agent.

149. Insight Imaging-Roanoke and its employees and agents uniformly misrepresented that the knock-off drug obtained from NECC and injected into Mr. Wingate's spinal canal was, in fact, the name brand drug produced by Pfizer from an FDA-regulated laboratory and/or they misrepresented that it was the generic drug produced by the FDA-regulated laboratory, Teva Parenteral Medicines, Inc. Both representations were false.

150. A redacted true and correct copy of a representative page from Mr. Wingate's medical/billing records from Insight Imaging-Roanoke is attached as **Exhibit F**.

151. At all times and places pertinent to this action, the methylprednisolone acetate that Insight Imaging-Roanoke and its employees and agents voluntarily purchased from NECC and then sold and provided to their patients, including Mr. Wingate, was contaminated with fungus, mold, and/or other contaminants.

Mr. Wingate's Medical Timeline and Death

152. Mr. Wingate and his wife, Sharon, planned a cruise to celebrate their 25<sup>th</sup> wedding anniversary.

153. In order to more fully enjoy this special trip, Mr. Wingate spoke to his doctor about relieving the pain in his shoulder caused by a narrowing of his spine in the region of his neck.

154. Mr. Wingate was referred by his family practice physician for an epidural steroid injection.

155. The typical method for receiving an epidural steroid injection requires imaging capability, such as a fluoroscope, that allows the proper placement of the injection in exactly the correct place.

156. An anesthesiologist or an interventional radiologist typically performs an epidural steroid injection.

157. The first facility to which Mr. Wingate's doctor referred him could not provide the injection in time for the planned anniversary cruise, so Mr. Wingate obtained an appointment at Insight Imaging-Roanoke to receive the epidural steroid injection that would alleviate his pain.

158. On September 6, 2012 Mr. Wingate received the epidural steroid injection at Insight Imaging-Roanoke.

159. Mr. Wingate's epidural steroid injection was administered by Dr. O'Brien.



160. Unbeknownst to Mr. Wingate, the epidural steroid injection contained the adulterated drug that Insight Imaging-Roanoke and its employees and agents had purchased from NECC.

161. Within days of the epidural steroid injection, Mr. Wingate began suffering headaches.

162. By September 11, 2012 Mr. Wingate was confined to bed with a painful headache.

163. On September 12, 2012, at the insistence of his wife, Mr. Wingate was taken to the emergency room at a local hospital.

164. Upon taking his medical history and learning his symptoms, the emergency room medical staff tested for and confirmed he suffered from meningitis.

165. Mr. Wingate was admitted to the hospital and given antibiotics intravenously for the meningitis.

166. By September 14, 2012 Mr. Wingate's symptoms had worsened including, but not limited to, he was experiencing increasing sensitivity to light and noise.

167. While alert, Mr. Wingate would ask his medical providers if he would be well soon enough to go on the long anticipated cruise with his wife.

168. In the evening of September 14, 2012 Mr. Wingate suffered a series of strokes and became unresponsive, so he was transferred to the Intensive Care Unit.

169. On September 16, 2012 Mr. Wingate was confused but able to communicate to his wife.

170. However, Mr. Wingate then experienced more strokes and seizures in the evening, leaving him unresponsive and his brain activity ceased.



171. Mr. Wingate died on September 18, 2012 at the age of 47 when he was removed from life support.

172. Mr. Wingate's funeral was conducted on the same day he and his wife planned to leave on their anniversary cruise.

173. Mr. Wingate left behind a wife and two teenage children.

174. The medical examiner has confirmed the cause of Mr. Wingate's death as fungal meningitis.

175. Mr. Wingate's death was caused by his fungal meningitis.

176. Mr. Wingate's strokes were caused by his fungal meningitis.

177. Mr. Wingate's fungal meningitis was caused by the epidural steroid injection that he received on September 6, 2012 at Insight Imaging-Roanoke by Dr. O'Brien.

178. Mr. Wingate's fungal meningitis was the result of the actions by Insight Imaging-Roanoke and its employees and agents in purchasing a contaminated and adulterated drug from a highly questionable compounding pharmacy and then providing it to Mr. Wingate.

179. As the result of Mr. Wingate's untimely death, Mrs. Wingate is entitled to the recovery of funeral, burial, and medical expenses, as well as damages for her and their children's extreme mental anguish, sorrow, loss of companionship, loss of comfort, loss of guidance, loss of kindly offices, loss of services, and all other items of damage provided by the Virginia Death by Wrongful Act statutes.

180. This lawsuit seeks fair compensation to the fullest extent permitted under the law of the Commonwealth of Virginia for Mr. Wingate's premature, painful, and agonizing death.

**COUNT I – NEGLIGENCE *PER SE***

181. The preceding paragraphs are hereby incorporated as if they were fully set forth herein.

182. Virginia Code § 8.01-221 establishes that a person who is harmed by violation of a statute may recover for such harm.

183. Virginia law also establishes that:

. . . the violation of a statute or municipal ordinance adopted for public safety constitutes negligence because the violation is the failure to abide by a particular standard of care prescribed by a legislative body. A party relying on negligence *per se* does not need to establish common law negligence provided the proponent of the doctrine produces evidence supporting a determination that the opposing party violated a statute enacted for public safety, that the proponent belongs to the class of persons for whose benefit the statute was enacted and the harm suffered was of the type against which the statute was designed to protect, and that the statutory violation was a proximate cause of the injury. Halterman v. Radisson Hotel Corp., 259 Va. 171, 176-77, 523 S.E. 2d 823, 825 (2000); Virginia Elec. & Power Co. v. Savoy Constr. Co., 224 Va. 36, 45, 294 S.E. 2d 811, 817 (1982).

Schlimmer v. Poverty Hunt Club, 268 Va. 74, 78-79, 597 S.E.2d 43, 46 (2004) (quotations omitted).

184. Virginia Code §§ 54.1-3400 *et seq.* (collectively known as “The Drug Control Act”) are statutes enacted for public safety, in that they protect the public from the release of substandard and otherwise unreasonably dangerous pharmaceutical drugs and drugs into the stream of Virginia commerce.

185. As a Virginia citizen and consumer of a drug regulated by the Virginia Drug Control Act, Mr. Wingate belonged to the class of persons for whose benefit those statutes were enacted.

186. A drug is deemed adulterated under Virginia law if it has been produced, prepared, packed, or held under insanitary conditions whereby it has been rendered injurious to health. Va. Code § 54.1-3461(A)(2).

187. Additionally, a drug is considered adulterated if it purports to be a drug recognized in an official compendium, but fails to meet the quality or purity standards set forth in the compendium or the federal act. Va. Code § 54.1-3461(B).

188. By holding and offering for sale an adulterated drug to its patients, including Mr. Wingate, Insight Imaging-Roanoke and its employees and agents violated Virginia Code § 54.1-3457(1), which is part of the Virginia Drug Control Act.

189. By receiving an adulterated drug in commerce and then delivering the drug for pay to its patients, including Mr. Wingate, Insight Imaging-Roanoke and its employees and agents violated Virginia Code § 54.1-3457(3), which is part of the Virginia Drug Control Act.

190. Mr. Wingate died as the result of the actions of Insight Imaging-Roanoke and its employees and agents in receiving, holding, selling, and providing to him an adulterated drug.

191. The adulterated drug injected into Mr. Wingate's spinal canal contained fungal pathogens that proximately caused him to develop fungal meningitis.

192. Death or injury of a patient resulting from consumption of or contact with adulterated drugs belongs to the category of harms against which the Virginia Drug Control Act was designed to protect.

193. Death or injury of a patient resulting from consumption of or contact with adulterated drugs distributed wholesale by an entity engaging in the wholesale distribution of prescription drugs in the Commonwealth of Virginia without a valid license belongs to the category of harms against which Virginia Drug Control Act was designed to protect.

194. Therefore, each of the violations of the above statutes (Virginia Code § 54.1-3457(1), and Virginia Code § 54.1-3457(3)) by Insight Imaging-Roanoke and its employees and agents constitutes negligence *per se*, and Mrs. Wingate is entitled to the recovery of funeral,

burial, and medical expenses, as well as damages for her and their children's extreme mental anguish, sorrow, loss of companionship, loss of comfort, loss of guidance, loss of kindly offices, loss of services, and all other items of damage provided by the Virginia Death by Wrongful Act statutes.

**COUNT II – VIRGINIA CONSUMER PROTECTION ACT**

195. The preceding paragraphs are hereby incorporated as if they were fully set forth herein.

196. Mr. Wingate engaged in a consumer transaction with Insight Imaging-Roanoke and its employees and agents as defined in Virginia Code § 59.1-198.

197. Insight Imaging-Roanoke and its employees and agents were suppliers of the tainted methylprednisolone acetate injected into Mr. Wingate's spinal canal.

198. Insight Imaging-Roanoke and its employees and agents violated Virginia Code § 59.1-200, which prohibits suppliers from misrepresenting goods as those of another, misrepresenting the source, sponsorship, approval or certification of goods, and misrepresenting that goods are of a particular standard, quality, grade or model.

199. These willful violations by Insight Imaging-Roanoke and its employees and agents resulted in Mr. Wingate's death.

200. Mrs. Wingate is entitled to the recovery of funeral, burial, and medical expenses, as well as damages for her and their children's extreme mental anguish, sorrow, loss of companionship, loss of comfort, loss of guidance, loss of kindly offices, loss of services, and all other items of damage provided by the Virginia Death by Wrongful Act statutes.

201. All of these actual damages occurred as the result of the violations of Virginia Code § 59.1-200 by Insight Imaging-Roanoke and its employees and agents.

202. Further, Mrs. Wingate is entitled to treble damages and an award of attorneys' fees, costs, and expenses incurred in this matter.

### **COUNT III – NEGLIGENCE**

203. The preceding paragraphs are hereby incorporated as if they were fully set forth herein.

204. Insight Imaging-Roanoke and its employees and agents had a duty to exercise reasonable care to ensure that the drugs that they purchased in order to sell and inject in their patients, including Mr. Wingate, came from drug companies that complied with Virginia laws regarding pharmaceutical drugs ("The Virginia Drug Control Act" statutes).

205. Insight Imaging-Roanoke and its employees and agents had a duty to exercise reasonable care to ensure that their purchase of the drug they provided to Mr. Wingate complied with the Virginia Drug Control Act.

206. Insight Imaging-Roanoke and its employees and agents had a duty to exercise reasonable care to ensure that the drugs they purchased in order to sell and administer to their patients, including Mr. Wingate, were purchased from drug manufacturers that utilized proper quality control, safety, and sterility measures in order to minimize the possibility that the drugs would become adulterated.

207. Insight Imaging-Roanoke and its employees and agents had a duty to inform the doctors practicing at it, including Drs. Mathis and O'Brien, about the purchasing decisions by Insight Imaging-Roanoke to obtain drugs from NECC and about NECC. To the extent that they did not do so, they violated their duty and their violation prevented the doctors practicing at it, including Drs. Mathis and O'Brien, from making knowledgeable and professionally reasonable decisions to reject such drug on behalf of Mr. Wingate and their other patients.

208. Insight Imaging-Roanoke and its employees and agents had a duty to provide adequate medical oversight regarding the purchase of drugs such as the one at issue in this case. To the extent that Insight Imaging-Roanoke had no official medical director during the time and places pertinent to this action, then they delegated to non-medical staff the important patient care function of choosing safe drugs for their patients.

209. Insight Imaging-Roanoke and its employees and agents had a duty to exercise reasonable care to avoid injecting Mr. Wingate with adulterated drugs.

210. Insight Imaging-Roanoke and its employees and agents had a duty to know what they were injecting into patients, including Mr. Wingate.

211. Insight Imaging-Roanoke and their employees and agents had a duty to provide Mr. Wingate reasonable care and treatment when he came to them for treatment.

212. Insight Imaging-Roanoke and its employees and agents had a duty to obtain informed consent from Mr. Wingate for the procedure performed on him, adequately and accurately describing to him the nature of the procedure, as well as the risks of such procedure.

213. In this case, where the methylprednisolone acetate came from an unaccredited, mass producing, out-of-state, compounding pharmacy, (unregulated by the FDA and surrounded by a garbage and waste facility), Insight Imaging-Roanoke and its employees and agents had a duty to inform Mr. Wingate of the source of the drug and the dangers associated therewith.

214. Insight Imaging-Roanoke and its employees and agents breached their duties to Mr. Wingate in many respects:

- a. They failed to exercise reasonable and prudent care to ensure that the drug they purchased and provided to Mr. Wingate was made in compliance with Virginia pharmaceutical laws;
- b. They failed to exercise reasonable and prudent care to ensure that the drug they purchased and provided to Mr. Wingate was sold to them in compliance with Virginia pharmaceutical laws;



- c. They failed to know and understand the source and supply of the drug they provided to Mr. Wingate;
- d. They failed to exercise reasonable and prudent care to ensure that the drug they provided to Mr. Wingate was produced in sanitary, sterile conditions;
- e. They failed to properly inform Mr. Wingate that the epidural steroid injection was an “off-label” application of the drug at issue, not approved by the FDA for such an application;
- f. They failed to properly inform Mr. Wingate of the risks and dangers associated with the injection of the drug; and they failed to inform him that they had obtained the drug from NECC, the mass-producing, unaccredited, non-FDA regulated compounding pharmacy surrounded by a garbage recycling facility;
- g. Alternatively to the preceding allegation, to the extent that Insight Health unilaterally made the decision to purchase the tainted steroid and kept important information regarding the actual source and identity of the methylprednisolone acetate from Drs. Mathis and O’Brien, it failed to exercise reasonable and prudent care to ensure that Mr. Wingate’s physician was adequately informed so as to allow his doctor to make knowledgeable and professionally reasonable decisions to reject such drug on behalf of Mr. Wingate and other similarly situated patients;
- h. They failed to exercise reasonable care to avoid injecting Mr. Wingate with an adulterated drug;
- i. To the extent that Insight Imaging – Roanoke had no official medical director (who would have reviewed the source and supply of drugs) during the time periods relevant to this proceeding, then all or some of the defendants delegated to non-medical staff the important patient care function of choosing safe drugs for patients; and they deviated from the standard of care and breached their duties in so doing;
- j. They failed to act ethically;
- k. They failed to act with integrity;
- l. They failed to put patient care first;
- m. They failed to do the right thing;
- n. They put profits over ethics;
- o. They put profits over integrity;
- p. They put profits over patient care; and
- q. In such other manners as may be shown through discovery and at trial.

215. The negligence of Insight Imaging-Roanoke and its employees and agents proximately caused Mr. Wingate's death.

216. Mrs. Wingate is entitled to the recovery of funeral, burial, and medical expenses, as well as damages for her and her children's extreme mental anguish, sorrow, loss of companionship, loss of comfort, loss of guidance, loss of kindly offices, loss of services, and all other items of damage provided by the Virginia Death by Wrongful Act statutes.

#### **COUNT IV – GROSS NEGLIGENCE**

217. The preceding paragraphs are hereby incorporated as if they were fully set forth herein.

218. The foregoing acts and omissions by Insight Imaging-Roanoke and its employees and agents went beyond mere thoughtlessness, inadvertence or error of judgment.

219. Rather, the actions of Insight Imaging-Roanoke and its employees and agents did not meet even the most minimal diligence to ensure that they were not injecting adulterated and tainted drugs directly into the bodies of their patients, including Mr. Wingate.

220. The acts and omissions of Insight Imaging-Roanoke and its employees and agents constituted such utter disregard for the rights of others, and such utter disregard for prudence, that they amount to complete neglect of the safety of patients, including Mr. Wingate.

221. The acts and omissions of Insight Imaging-Roanoke and its employees and agents were a heedless and palpable violation of their legal duties respecting the life and rights of Mr. Wingate. Frazier v. City of Norfolk, 234 Va. 388, 393, 362 S.E.2d 688, 691 (1987).

222. Mr. Wingate's death occurred as a proximate result of the grossly negligent acts and omissions of Insight Imaging-Roanoke and its employees and agents.



**COUNT V – FRAUD**

223. The preceding paragraphs are hereby incorporated as if they were fully set forth herein.

224. Insight Imaging-Roanoke and its employees and agents did not inform their patients, including Mr. Wingate, that they were providing drugs produced from a compounding pharmacy, much less a compounding pharmacy with the characteristics and problems described in the preceding paragraphs.

225. Insight Imaging-Roanoke and their employees and agents had a duty to inform their patients of these facts which were possessed solely by them and which they knew were unknown to Mr. Wingate and other patients.

226. The decision by Insight Imaging-Roanoke and its employees and agents not to do so constituted actual and/or constructive fraud.

227. Insight Imaging-Roanoke and its employees and agents had a duty to adequately inform the doctors practicing at it, including Drs. Mathis and O'Brien, about the purchasing decisions by Insight Imaging-Roanoke to obtain drugs from NECC and about NECC. To the extent that they did not do so, they violated their duty and their violation prevented the doctors practicing at it, including Drs. Mathis and O'Brien, from making knowledgeable and professionally decisions to reject such drugs on behalf of Mr. Wingate and their other patients.

228. Insight Imaging-Roanoke and its employees and agents provided patients, such as Mr. Wingate, with written false documentation asserting that the drug injected was, in fact, the name brand drug produced by the FDA-regulated manufacturer, Pfizer.

229. Also, Insight Imaging-Roanoke and its employees and agents provided patients, such as Mr. Wingate, with written false drug code documentation asserting that the drug injected

into the patient was, in fact, the generic version of the drug produced by the FDA-regulated manufacturer, Teva Parenteral Medicines, Inc., National Drug Code, 0703-0051-01 (single dose, 80 mg/mL, preservative free, methylprednisolone acetate).

230. Within the context of the healthcare provider-patient relationship, Mr. Wingate relied upon the superior knowledge of Insight Imaging-Roanoke and its employees and agents concerning the drug, source of the drug, and cost of the drug in accepting their representation that the methylprednisolone acetate was safe and effective.

231. Insight Imaging-Roanoke and its employees and agents provided Mr. Wingate with a knock-off drug obtained from an unaccredited compounding pharmacy, unregistered to distribute wholesale in Virginia, and not preferred by insurance companies – including Mr. Wingate’s insurance company, without disclosing information about its source.

232. In so doing, Insight Imaging-Roanoke and its employees and agents concealed facts material to Mr. Wingate’s treatment, knowing Mr. Wingate acted on the belief that no such facts existed, and that Mr. Wingate relied upon it to obtain and inject safe drugs.

233. By representing that the drug injected was obtained from an FDA-regulated manufacturer, Insight Imaging-Roanoke and its employees and agents misrepresented a material fact regarding Mr. Wingate’s treatment.

234. Rather than properly informing its patients, including Mr. Wingate, of these crucial facts, Insight Imaging-Roanoke and its employees and agents falsely represented the drug at issue as “Depo-Medrol,” the trademarked name brand used by Pfizer; and falsely coded it as the generic version of the drug produced by the FDA-regulated manufacturer, Teva Parenteral Medicines, Inc., National Drug Code, 0703-0051-01 (single dose, 80 mg/mL, preservative free, methylprednisolone acetate).

235. This pattern of deception by Insight Imaging-Roanoke and its employees and agents was repeated to Mr. Wingate's primary care physician.

236. This pattern of deception by Insight Imaging-Roanoke and its employees and agents was also repeated for billing purposes to Mr. Wingate's insurance company, where Insight Imaging-Roanoke falsely used the National Drug Code, 0703-0051-01, a unique product code assigned to the completely unrelated FDA-regulated drug manufacturer, Teva Parenteral Medicines, Inc.

237. Insight Imaging-Roanoke also used an HCPCS "J" code inappropriate and misleading for compounded drugs.

238. Such actions by Insight Imaging-Roanoke and its employees and agents show affirmative misrepresentations of the identity of the drug provided to Mr. Wingate and a knowing, deliberate decision not to disclose the source of the "drug" provided to Mr. Wingate.

239. As a third party payor and agent authorized to receive medical invoices for processing on behalf of Mr. Wingate, misrepresentations to Mr. Wingate's health insurer constitute misrepresentations to him.

240. Mr. Wingate's health insurer, like many such third-party payors, maintains policies discouraging the use of compounded drugs.

241. For example, Anthem Blue Cross states as follows:

Compounded medications are customized medication(s) ... that are not commercially available ... However, they are not approved by the U.S. Food and Drug Administration (FDA) nor are they approved by our Pharmacy and Therapeutics process. **Since there is limited oversight in the preparation of these compounded medications, there is a possibility that patients may be put at risk when prescribed a compounded medication that is not subject to quality testing that validates purity, stability or dosage...** Thus, due to the lack of data to adequately review these medications, compounded medications are considered **non-preferred**... They may also require prior authorization of benefits for coverage through a participating network pharmacy...

242. On information and belief, Insight Imaging-Roanoke and its employees and agents knew that using drugs from compounding pharmacies would present billing issues and problems with reimbursement.

243. On information and belief, Insight Imaging-Roanoke and its employees and agents knew that properly coding the drugs injected into Mr. Wingate and other patients would cause concerns and “red flags” with insurance companies, such as the one serving Mr. Wingate.

244. Accordingly, on information and belief, Insight Imaging-Roanoke and its employees and agents specifically chose to falsely describe the drugs provided as part of a scheme and common practice or design, intended to prevent insurance companies from realizing the nature and source of the drugs being injected into patients, such as Mr. Wingate.

245. Insurance companies, such as the one serving Mr. Wingate, act as a protective information source and gatekeeper for their customers.

246. Here, Insight Imaging-Roanoke and its employees and agents engaged in the same pattern of behavior (and the same specific misrepresentations to patients, referring primary care physicians, and insurers provided by the defendants to Mr. Wingate, his doctor and his insurer) with many other patients receiving epidural steroid injections.

247. These specific actions relating to Mr. Wingate and the prolonged pattern of deception prevented Mr. Wingate’s insurer from properly performing its protective role. As a result, Insight Imaging-Roanoke was able to continue its practice of purchasing methylprednisolone acetate from NECC and passing it off as a manufactured and safe drug.

248. Under these circumstances, misrepresentations to Mr. Wingate’s insurer – particularly as part of a pattern of conduct – constituted misrepresentations to Mr. Wingate that were material and relied upon to his detriment.

249. Insight Imaging-Roanoke and its employees and agents misrepresented that the knock-off drug obtained from NECC and injected into Mr. Wingate's spinal canal was, in fact, the name brand drug produced by Pfizer from an FDA-regulated laboratory; they misrepresented the code for such drug as the generic drug produced by the FDA-regulated laboratory, Teva Parenteral Medicines, Inc.

250. These representations (and the pattern of which they were a part) were false and deceptive, were relied upon to the detriment of Mr. Wingate (and/or his agent insurer) and other patients, and caused harm to and the death of Mr. Wingate.

251. Insight Imaging-Roanoke and its employees and agents knew, or should have known, these representations to be false.

252. These representations and the pattern of similar behavior by Insight Imaging-Roanoke and its employees and agents constitute actual or constructive fraud.

#### **CERTIFICATION PURSUANT TO VIRGINIA CODE § 8.01-50.1**

253. Mrs. Wingate certifies that she complied with Virginia Code § 8.01-50.1 before requesting service of process upon the defendants.

#### **REQUEST FOR TRIAL BY JURY**

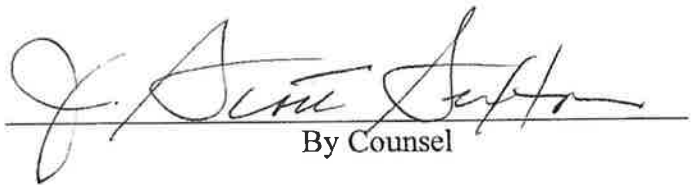
254. Mrs. Wingate requests trial by jury on all issues.

#### **PRAYER FOR RELIEF**

WHEREFORE, Sharon G. Wingate, Executor of the Estate of Douglas Gray Wingate, deceased, by counsel, moves this Court for judgment against the defendants, jointly and

severally, in the amount of TWENTY FIVE MILLION DOLLARS (\$25,000,000) plus her taxable costs with pre-verdict interest from September 6, 2012 and post-verdict interest on all of these amounts, as well as \$350,000 in punitive damages, trebled damages, attorney's fees, and costs.

SHARON G. WINGATE, EXECUTOR OF THE  
ESTATE OF DOUGLAS GRAY WINGATE,  
DECEASED,



By Counsel

J. Scott Sexton, Esq. (VSB No. 29284)  
Anthony M. Russell, Esq. (VSB No. 44505)  
Charles H. Smith, III, Esq. (VSB No. 32891)  
H. David Gibson, Esq. (VSB No. 40641)  
Benjamin D. Byrd, Esq. (VSB No. 76560)  
Daniel R. Sullivan, Esq. (VSB No. 81550)  
GENTRY LOCKE RAKES & MOORE, LLP  
10 Franklin Road, S.E., Suite 800  
P. O. Box 40013  
Roanoke, Virginia 24022-0013  
(540) 983-9300  
Fax: (540) 983-9400  
[sexton@gentrylocke.com](mailto:sexton@gentrylocke.com)  
[russell@gentrylocke.com](mailto:russell@gentrylocke.com)  
[smith@gentrylocke.com](mailto:smith@gentrylocke.com)  
[gibson@gentrylocke.com](mailto:gibson@gentrylocke.com)  
[byrd@gentrylocke.com](mailto:byrd@gentrylocke.com)  
[sullivan@gentrylocke.com](mailto:sullivan@gentrylocke.com)

*Counsel for Sharon G. Wingate, Executor of the  
Estate of Douglas Gray Wingate, deceased*





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EXHIBIT A



• **MAKE CHECKS PAYABLE TO:**

Insight Imaging Roanoke  
PO Box 843086

Los Angeles, CA 900843086

STATEMENT DATE	PAY THIS AMOUNT	ACCOUNT NBR
10/23/12	\$0.00	
		SHOW AMOUNT PAID HERE \$

## STATEMENT

**ADDRESSEE:**

WINGATE, DOUGLAS

## REMIT TO:

**Insight Imaging Roanoke**  
PO Box 843086  
Los Angeles, CA 900843086

☐ Please check box if above address is incorrect or insurance information has changed, and indicate change(s) on reverse side.

PLEASE DETACH AND RETURN TOP PORTION WITH YOUR PAYMENT

[illegible]

MESSAGE:

PLEASE PAY THIS AMOUNT »»»»»	\$0.00
---------------------------------	--------

**\*\* PAYMENT DUE UPON RECEIPT \* THANK YOU \*\***  
**STATEMENT**

EXHIBIT B

PAGE: 1



INSIGHT IMAGING - ROANOKE  
2921 FRANKLIN ROAD S.W.  
ROANOKE VA 24014

Tel: 540.581.0882  
Fax: 540.581.0881

www.insighthealth.com

Date: \_\_\_\_\_

Injection dosage: Depo-Medrol 80mg / 40mg

Steroids typically take 12 to 24 hours before they start to work.  
Maximum effect can take up to 7 - 10 days.

Call Insight Imaging (540-581-0882) in a week if symptoms have not subsided to schedule another injection. If you already have an appointment scheduled with Insight, keep that appointment unless otherwise directed by your physician.

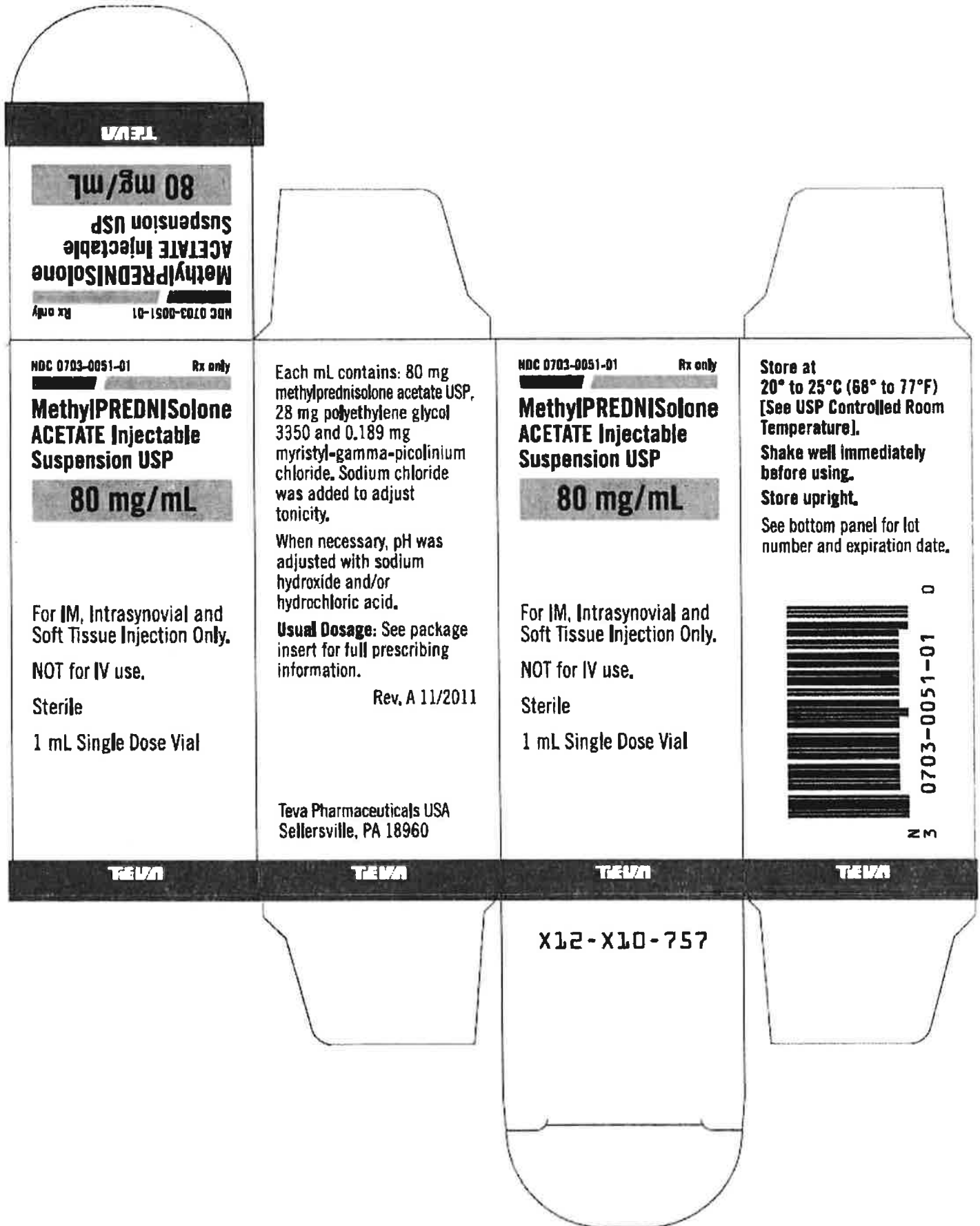
If your pain has completely resolved, and you no longer need your follow up appointment, please call Insight Imaging to cancel your future injection.

Continue to take pain meds if needed.  
Heat or ice may be used as well.

Symptoms can worsen before seeing improvement.

\*\*\*\*Call your Doctor that monitors your Diabetes or Blood Pressure if you feel you are higher than the guidelines set by your physician.

**PRINCIPAL DISPLAY PANEL**





**Insight Imaging – Roanoke**  
2923 Franklin Road  
Roanoke, VA 22206  
PH# 540.581.0882  
FAX# 540.581.0881

**PATIENT NAME:** WINGATE, DOUGLAS  
**PATIENT DOB:**  
**DATE OF EXAM:** 09/06/2012  
**REQUESTED BY:** CHRISTY ARTHUR, MD

**EXAM:** INJ 1 NOT LYTIC-W/WO CM-DX/TX-EPIDUR; CERV/THOR

**CLINICAL HISTORY:** Cervical radiculopathy.

**INJECTION SITE:** The study was performed near the midline at C5-C6.

Following sterile preparation and drape and with the use of lidocaine as local anesthetic, a 25-gauge spinal needle was advanced under fluoroscopic guidance to the posterior epidural space. The study was performed near the midline at C5-C6. Small puffs of contrast were administered to confirm needle tip location. Once needle tip location in the posterior epidural space was confirmed, a mixture of Depo-Medrol and saline was administered. A total 80 mg of Depo-Medrol was given. The patient tolerated the procedure well and left the department in stable condition.

**IMPRESSION:**  
SUCCESSFUL CERVICAL EPIDURAL STEROID INJECTION UNDER FLUOROSCOPIC GUIDANCE

Thank you for this referral.

Robert F. O'Brien, M.D.  
RFO/mm  
D: 09/06/2012 06:09:36PDT  
T: 09/06/2012 06:34:18PDT  
Doc ID: 12087066/Insight Job ID: 2315558/NTS Job ID: 2315558/10243381  
10243381  
Document authenticated by Robert F. O'Brien, M.D., on 09/06/2012 08:01:53PDT



Procedure Completion																													
<div> <div> </div> <div> Send HL7 Hx (0) </div> </div> <div>Exam 1 of 1</div>																													
Patient Name: WINGATE DOUGLAS DOB: Phone: Sex: M Age: 47 SSN: 					Visit Service Date: 9/6/2012 Appt Type: S		Is Patient Pregnant Yes Date of LMP: No MM/DD/YYYY																						
Accession	CPT Code	CPT Description	Modality	Start Time	End Time																								
10243381	62310	EPIDUR(ESI) CERV/TH	SPC	8:30 AM	9:00 AM																								
Performed Procedure: 10243381 Prim Diag: PD CPT Cd/Desc: 62310 EPIDUR(ESI) CERV/TH Copy: 1 Start/End: 8:40 AM 8:50 AM Qty: 1 Additional Charges: <input checked="" type="checkbox"/> HCPCS_A4649 - SURGICAL SUPPLY MISCELLANEOUS <input checked="" type="checkbox"/> 77003 - FLUOROSCOPIC GUIDANCE AND LOCALIZATION C Contrast Seq w/ Seq w/o Total 0 Radiologist: OBRIEN ROBERT Radiation Dose: No Dose Available DLP mGy-cm Cancellation:																													
Contrast/Isotope/Sedation/Supplies <table border="1"> <thead> <tr> <th>Bill Qty</th> <th>HCPCS Cd</th> <th>HCPCS Description</th> <th>NDC</th> <th>Accession</th> </tr> </thead> <tbody> <tr> <td>2</td> <td>Q9966</td> <td>LOW OSMOLAR CONTRAST MATERIAL, 200-299 MG/ML IODINE</td> <td>00270141125</td> <td>10243381</td> </tr> <tr> <td>1</td> <td>J1040</td> <td>INJECTION, METHYLPREDNISOLONE ACETATE, 80 MG</td> <td>00703005101</td> <td>10243381</td> </tr> <tr> <td>1</td> <td>A4216</td> <td>STERILE WATER, SALINE AND/OR DEXTROSE, DILUENT/FLUSH,</td> <td>00409488820</td> <td>10243381</td> </tr> </tbody> </table>										Bill Qty	HCPCS Cd	HCPCS Description	NDC	Accession	2	Q9966	LOW OSMOLAR CONTRAST MATERIAL, 200-299 MG/ML IODINE	00270141125	10243381	1	J1040	INJECTION, METHYLPREDNISOLONE ACETATE, 80 MG	00703005101	10243381	1	A4216	STERILE WATER, SALINE AND/OR DEXTROSE, DILUENT/FLUSH,	00409488820	10243381
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Sedation/Meds Brand: DEPO-MEDROL METHYLPREDNISOLONE Strength: 80 MG/ML Route: EPIDURAL Delivery: 1 VIL NDC #: 00703005101 Amt Admin: 1 ML Sedation Note: Lot #: 06292012 Exp. Dt: 12/26/2012 Admin By: RFO (Initials)					<input checked="" type="checkbox"/> Ok <input checked="" type="checkbox"/> Cancel																								



Roanoke City Circuit

Circuit Court

Sharon G. Wingate, Executor of the Estate of v./In re: John M. Mathis, M.D., Robert F. O'Brien, M.D.,  
PLAINTIFF(S) DEFENDANT(S)

Douglas Gray Wingate, deceased Insight Health Corp., d/b/a Insight Imaging and Image  
Guided Pain Management, P.C. d/b/a Insight Imaging Roanoke

I, the undersigned [ ] plaintiff [ ] defendant [x] attorney for [x] plaintiff [ ] defendant hereby notify the Clerk of Court that I am filing the following civil action. (Please indicate by checking box that most closely identifies the claim being asserted or relief sought.)

GENERAL CIVIL

Subsequent Actions

- ☐ Claim Impleading Third Party Defendant
  - ☐ Monetary Damages
  - ☐ No Monetary Damages
- ☐ Counterclaim
  - ☐ Monetary Damages
  - ☐ No Monetary Damages
- ☐ Cross Claim
- ☐ Interpleader
- ☐ Reinstatement (other than divorce or driving privileges)
- ☐ Removal of Case to Federal Court

Business & Contract

- ☐ Attachment
- ☐ Confessed Judgment
- ☐ Contract Action
- ☐ Contract Specific Performance
- ☐ Detinue
- ☐ Garnishment

Property

- ☐ Annexation
- ☐ Condemnation
- ☐ Ejectment
- ☐ Encumber/Sell Real Estate
- ☐ Enforce Vendor's Lien
- ☐ Escheatment
- ☐ Establish Boundaries
- ☐ Landlord/Tenant
  - ☐ Unlawful Detainer
- ☐ Mechanics Lien
- ☐ Partition
- ☐ Quiet Title
- ☐ Termination of Mineral Rights

Tort

- ☐ Asbestos Litigation
- ☐ Compromise Settlement
- ☐ Intentional Tort
- ☒ Medical Malpractice
- ☐ Motor Vehicle Tort
- ☐ Product Liability
- ☐ Wrongful Death
- ☐ Other General Tort Liability

ADMINISTRATIVE LAW

- ☐ Appeal/Judicial Review of Decision of (select one)
  - ☐ ABC Board
  - ☐ Board of Zoning
  - ☐ Compensation Board
  - ☐ DMV License Suspension
  - ☐ Employee Grievance Decision
  - ☐ Employment Commission
  - ☐ Local Government
  - ☐ Marine Resources Commission
  - ☐ School Board
  - ☐ Voter Registration
- ☐ Other Administrative Appeal

DOMESTIC/FAMILY

- ☐ Adoption
  - ☐ Adoption - Foreign
- ☐ Adult Protection
- ☐ Annulment
  - ☐ Annulment - Counterclaim/Responsive Pleading
- ☐ Child Abuse and Neglect - Unfounded Complaint
- ☐ Civil Contempt
- ☐ Divorce (select one)
  - ☐ Complaint - Contested\*
  - ☐ Complaint - Uncontested\*
  - ☐ Counterclaim/Responsive Pleading
  - ☐ Reinstatement - Custody/Visitation/Support/Equitable Distribution
- ☐ Separate Maintenance
  - ☐ Separate Maintenance Counterclaim

WRITS

- ☐ Certiorari
- ☐ Habeas Corpus
- ☐ Mandamus
- ☐ Prohibition
- ☐ Quo Warranto

PROBATE/WILLS AND TRUSTS

- ☐ Accounting
- ☐ Aid and Guidance
- ☐ Appointment (select one)
  - ☐ Guardian/Conservator
  - ☐ Standby Guardian/Conservator
- ☐ Trust (select one)
  - ☐ Impress/Declare
  - ☐ Reformation
- ☐ Will (select one)
  - ☐ Construe
  - ☐ Contested

MISCELLANEOUS

- ☐ Appointment (select one)
  - ☐ Church Trustee
  - ☐ Conservator of Peace
  - ☐ Marriage Celebrant
- ☐ Bond Forfeiture Appeal
- ☐ Declaratory Judgment
- ☐ Declare Death
- ☐ Driving Privileges (select one)
  - ☐ Reinstatement pursuant to § 46.2-427
  - ☐ Restoration - Habitual Offender or 3<sup>rd</sup> Offense
- ☐ Expungement
- ☐ Firearms Rights - Restoration
- ☐ Forfeiture of U.S. Currency
- ☐ Freedom of Information
- ☐ Injunction
- ☐ Interdiction
- ☐ Interrogatory
- ☐ Judgment Lien-Bill to Enforce
- ☐ Law Enforcement/Public Official Petition
- ☐ Name Change
- ☐ Referendum Elections
- ☐ Sever Order
- ☐ Taxes (select one)
  - ☐ Correct Erroneous State/Local
  - ☐ Delinquent
- ☐ Vehicle Confiscation
- ☐ Voting Rights - Restoration
- ☐ Other (please specify)

[x] Damages in the amount of \$ 25,000,000.00 are claimed.

12-27-12  
DATE

[ ] PLAINTIFF [ ] DEFENDANT [x] ATTORNEY FOR [x] PLAINTIFF  
[ ] DEFENDANT

J. Scott Sexton, Esq. / Gentry Locke Rakes & Moore, LLP  
PRINT NAME

10 Franklin Road, SE, Suite 800, P.O. Box 40013  
ADDRESS/TELEPHONE NUMBER OF SIGNATOR

Roanoke, VA 24022-0013 540-983-9300

\*"Contested" divorce means any of the following matters are in dispute: grounds of divorce, spousal support and maintenance, child custody and/or visitation, child support, property distribution or debt allocation. An "Uncontested" divorce is filed on no fault grounds and none of the above issues are in dispute.

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF VIRGINIA  
ROANOKE DIVISION**

**SHARON G. WINGATE, EXECUTOR OF  
THE ESTATE OF DOUGLAS GRAY  
WINGATE, DECEASED,**

**Plaintiff,**

**v.**

**Civil Action No.:** \_\_\_\_\_

**NEW ENGLAND COMPOUNDING  
PHARMACY, INC. D/B/A NEW ENGLAND  
COMPOUNDING CENTER**

**Serve: Gregory Conigliaro, Its Registered Agent )  
697 Waverly Street )  
Framingham, MA 01701, )**

**MEDICAL SALES MANAGEMENT, INC. )  
Serve: Gregory Conigliaro, Its Registered Agent )  
697 Waverly Street )  
Framingham, MA 01701, )**

**and**

**BARRY J. CADDEN,  
Serve at: 13 Manchester Drive  
Wrentham, MA 02093**

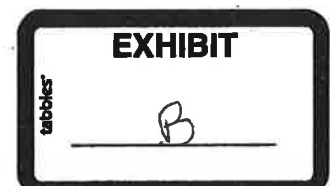
**Defendants.**

**COMPLAINT**

Sharon G. Wingate, Executor of the Estate of Douglas Gray Wingate, deceased, by counsel, states this Complaint against New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center (“NECC”), Medical Sales Management, Inc. (“MSM”), and Barry J. Cadden (“Cadden”) (hereinafter collectively referred to as the “defendants”):

**Preliminary Statement**

1. This lawsuit arises from the untimely death of Douglas Gray Wingate (“Mr.



Wingate”). To more fully enjoy the 25<sup>th</sup> wedding anniversary trip he had planned with his wife, Mr. Wingate received a medically prescribed epidural steroid injection in his neck on September 6, 2012. Being in otherwise very good health, the purpose of the injection was to relieve shoulder pain associated with narrowing (stenosis) in his cervical spine. He died 12 days later at the age of 47 because the steroid shot, manufactured, advertised and distributed by the defendants, was adulterated and contaminated with fungus or mold bearing pathogens that were injected into his central nervous system along with the immune system suppressing steroid. As the fungus grew inside Mr. Wingate’s spinal fluid, he developed fungal meningitis, severely inflaming the tissues lining his brain and spinal cord. Ultimately, the pressure created inside Mr. Wingate’s skull led to deep brain strokes, seizures and, ultimately, death. He left behind a wife and two teenage children as statutory beneficiaries. This lawsuit seeks compensation from the defendants for Mr. Wingate’s death.

### **Parties**

2. On September 18, 2012, Mr. Wingate died as a result of brain damage and other complications associated with fungal meningitis.

3. On October 5, 2012, Mr. Wingate’s wife, Sharon G. Wingate (“Mrs. Wingate” or the “Executor”) duly qualified as the Executor of Mr. Wingate’s Estate in the Commonwealth of Virginia.

4. Mr. Wingate was a citizen of the Commonwealth of Virginia.

5. NECC is a Massachusetts corporation that maintains its principal place of operations at 697 Waverly Street, in Framingham, Massachusetts.

6. MSM is a Massachusetts corporation that maintains its principal place of operations at 701 Waverly Street, Framingham, Massachusetts.

7. Cadden, who was at all relevant times the responsible pharmacist for NECC, is a Massachusetts resident.

### **Jurisdiction and Venue**

8. This matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.

9. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a).

10. A substantial part of the events or omissions giving rise to this claim occurred in this judicial district.

11. Venue is proper in this Court pursuant to at least 28 U.S.C. § 1391(b)(2).

### **Factual Background**

#### **The Defendants' Operations**

12. NECC is jointly owned by Cadden, his wife, Lisa Cadden and her brother, Gregory Conigliaro.

13. The defendants operated a compounding pharmacy in Framingham, Massachusetts.

14. Compounding pharmacies engage in mixing (or “compounding”) drug products for specific patients, pursuant to a valid prescription.

15. Because they typically compound drug products in forms that are not commercially available, compounding pharmacies are not regulated by the FDA.

16. Rather, compounding pharmacies are generally regulated under state law applicable to pharmacies and pharmacists. Although it operates in Massachusetts, NECC must also comply with Virginia law in order to fill prescriptions in Virginia. It must be licensed and registered with the Virginia Board of Pharmacy.



17. MSM is a separate corporate entity from NECC. Upon information and belief, at all relevant times, MSM served as the marketing arm for New England Compounding, providing marketing and advertising services, promoting the compounding business at medical trade shows nationwide, “cold-calling” potential customers, calling existing customers, and managing NECC’s online operations.

18. Cadden is the pharmacist in charge of NECC’s operations, and was listed as such in NECC’s registration as a nonresident pharmacy in Virginia.

19. As pharmacist in charge, Cadden was at all relevant times personally responsible to ensure that NECC’s operations complied with Virginia laws. Va. Code § 54.1-3434.1 (any non-resident pharmacy “*shall designate a pharmacist in charge who is licensed as a pharmacist in Virginia and is responsible for the pharmacy's compliance with this chapter . . .*” (emphasis added).

20. Furthermore, as pharmacist in charge of NECC, Cadden was at all times personally responsible to supervise NECC’s operations at its facility in Framingham, Massachusetts. Va. Code § 54.1-3432 (“Every pharmacy shall be under the *personal supervision* of a pharmacist on the premises of the pharmacy.”) (emphasis added).

21. The defendants are in the business of compounding and manufacturing medications and drugs, including methylprednisolone acetate. The brand name of this drug, Depo-Medrol, is produced by the FDA-regulated company, Pharmacia & Upjohn Company, a Division of Pfizer, Inc. Other FDA-regulated drug manufacturers produce generic versions of this drug.

22. Rather than producing small quantities of this knock-off Depo-Medrol, NECC produced vast batches of this drug, thousands at a time. It then acted as a wholesale distributor.

23. The defendants compounded and manufactured medications, including methylprednisolone acetate, that were contaminated with fungus, mold and other contaminants.

24. Under Virginia Code §54.1-3435.01(A), non-resident pharmacies that engage in wholesale distribution of prescription drugs into the Commonwealth of Virginia must register with the Virginia Board of Pharmacy, in addition to registering as a non-resident pharmacy.

25. NECC is and was registered in the Commonwealth of Virginia as a non-resident pharmacy, but is not and was not registered as a wholesale distributor of prescription drugs as required by Virginia Code §54.1-3435.01(A).

26. Under Virginia law, the compounding pharmacist must ensure compliance with USP-NF standards (United States Pharmacopeial National Formulary). Virginia Code § 54.1-3410.2(E).

27. Pharmacists and pharmacies may not engage in “the regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products.” Virginia Code § 54.1-3410.2(H)(2).

28. As well as other drugs, the defendants produced methylprednisolone acetate without preservative, which they then sold to clinics, hospitals and other healthcare providers in bulk, packaging the drug in single dosage vials.

29. Such large-scale production of a commercially available drug is illegal under Virginia Code § 54.1-3410.2(H)(2).

30. NECC is not accredited by the Pharmacy Compounding Accreditation Board (“PCAB”) or any other similar organization, such as The Joint Commission, that offers independent assurance as to the quality and competence of compounding pharmacies that meet certain requirements.

31. The drug at issue was to be used in epidural steroid injections allowing direct contact with the central nervous system. It was produced from non-sterile ingredients which then had to be

rendered sterile as a finished product, thus making the methylprednisolone acetate a high-risk compound. It was also produced without preservatives. Thus, although all drugs should be produced in a highly sterile environment, these drugs in particular must be. Additionally, sterilization techniques and sterility testing are crucial to properly producing such drugs.

32. However, the defendants purposefully maintained the supposedly sterile NECC pharmacy in an aged building that is surrounded by a waste recycling center owned by one of the co-owners of NECC, Gregory Conigliaro. This facility, called Conigliaro Enterprises, receives many varieties of garbage and waste which are sorted, stored, and manipulated just outside the back door of the NECC facility. A photograph showing the rear wall and backyard of the “pharmacy” is attached as **Exhibit A**.

33. It is difficult to distinguish where NECC ends and the waste recycling center begins, if there is such a distinction in fact; but, the waste facility lists its address as 701 Waverly Street, Framingham, Massachusetts, and operates under the name “Conigliaro Industries.” NECC lists its address as 697 Waverly Street. MSM lists its address as 701 Waverly Street, the same as Conigliaro Industries.

34. The conditions in which the defendants produced their products were unsanitary and unsterile. NECC failed to meet basic quality and sterility standards; and it failed to properly test the drugs at issue for sterility prior to releasing them. As a result, thousands of adulterated products manufactured by NECC were then released into the stream of commerce throughout the United States of America, including at least two clinics in the Commonwealth of Virginia.

35. The drug at issue in this case is a steroid which the defendants knew would be injected into patients so as to enter or potentially enter the central nervous system. The defendants also knew that such steroids act as immune-suppressing agents, thus weakening the patient’s natural

ability fight off pathogens that could possibly be included in the injection. The defendants also knew that the central nervous system is a relatively closed system, making treatment options more difficult in the event of an adulterated invasion. Notwithstanding this knowledge, the defendants chose to operate NECC's facility in the same complex as the waste facility, chose to produce such drugs in bulk batches (making mistakes more likely), chose not to properly sterilize the drugs, and chose not to have the drugs sufficiently tested by an FDA-approved testing facility before release for sale.

#### Mr. Wingate's Medical Timeline and Death

36. Mr. Wingate and his wife, Sharon, planned a cruise to celebrate their 25<sup>th</sup> wedding anniversary. In order to more fully enjoy this special trip, Mr. Wingate spoke to his doctor about relieving the pain in his shoulder caused by a narrowing of his spine in the region of his neck (cervical).

37. Mr. Wingate was referred by his family practice physician for an epidural steroid injection. The typical method for receiving such an injection requires radiological facilities that allow the proper placement of the shot in exactly the right place with the assistance of equipment such as a fluoroscope. An anesthesiologist or an interventional radiologist usually performs such a procedure.

38. The first facility to which his doctor referred him could not provide the shot in time for the planned anniversary cruise, so Mr. Wingate obtained an appointment at Insight Imaging - Roanoke, a clinic in Roanoke, Virginia, to receive the epidural steroid injection that would alleviate his pain.

39. Mr. Wingate received the injection at the clinic on September 6, 2012.

40. Within days of the injection, Mr. Wingate began suffering headaches.

41. By September 11, 2012, Mr. Wingate was confined to bed with a painful headache.

42. On September 12, 2012, on the insistence of his wife, Mr. Wingate was taken to the emergency room at LewisGale Medical Center.

43. Upon taking his medical history and learning his symptoms, the emergency room medical staff tested for and confirmed he suffered from meningitis. Mr. Wingate was admitted to the hospital and given antibiotics intravenously for the meningitis.

44. By September 14, 2012, Mr. Wingate's symptoms had worsened; he was experiencing increasing sensitivity to light and noise.

45. In the evening of September 14, 2012, Mr. Wingate suffered a series of strokes and was unresponsive; he was placed in the Intensive Care Unit.

46. On Sunday, September 16, 2012, Mr. Wingate was confused but able to communicate to his wife. However, he then experienced more strokes and seizures in the evening, leaving him unresponsive. His brain activity ceased.

47. Mr. Wingate died on September 18, 2012 when he was removed from life support.

48. The medical examiner has since confirmed that the cause of Mr. Wingate's death was fungal meningitis.

49. Mr. Wingate's fungal meningitis was a direct and proximate result of having methylprednisolone acetate made by the defendants and contaminated with fungus, mold and other contaminants injected into his central nervous system.

50. Mr. Wingate's death occurred as a direct and proximate result of having methylprednisolone acetate made by the defendants and contaminated with fungus, mold and other contaminants injected into his body.

51. As a proximate result of the defendants' actions, Mr. Wingate's beneficiaries have suffered extreme mental anguish, sorrow, loss of companionship, comfort, guidance, kindly offices, invaluable services, and all other items of damage provided by the Virginia Death by Wrongful Act statutes. Code Ann. § 8.01-50, et seq.

### **COUNT I: NEGLIGENCE *PER SE***

52. The plaintiff hereby incorporates each of the preceding paragraphs as if set forth fully herein.

53. Virginia Code Section 8.01-221 establishes that a person who is harmed by violation of a statute may recover for such harm.

54. Virginia law also establishes that:

. . . the violation of a statute or municipal ordinance adopted for public safety constitutes negligence because the violation is the failure to abide by a particular standard of care prescribed by a legislative body. A party relying on negligence *per se* does not need to establish common law negligence provided the proponent of the doctrine produces evidence supporting a determination that the opposing party violated a statute enacted for public safety, that the proponent belongs to the class of persons for whose benefit the statute was enacted and the harm suffered was of the type against which the statute was designed to protect, and that the statutory violation was a proximate cause of the injury. Halterman v. Radisson Hotel Corp., 259 Va. 171, 176-77, 523 S.E. 2d 823, 825 (2000); Virginia Elec. & Power Co. v. Savoy Constr. Co., 224 Va. 36, 45, 294 S.E. 2d 811, 817 (1982)

Schlimmer v. Poverty Hunt Club, 268 Va. 74, 78-79, 597 S.E.2d 43, 46 (2004) (quotations omitted).

55. Virginia Code Sections 54.1-3400 et seq. (collectively known as "The Drug Control Act") are statutes enacted for public safety, in that they protect the public from the release of substandard and otherwise unreasonably dangerous pharmaceutical drugs and medications into the stream of Virginia commerce.

56. As a Virginia resident and consumer of a drug regulated by the Virginia Drug Control Act, Mr. Wingate belonged to the class of persons for whose benefit those statutes were enacted.

57. A drug is deemed adulterated under Virginia law if it has been produced, prepared, packed, or held under insanitary conditions whereby it has been rendered injurious to health. Va. Code §54.1-3461(A)(2).

58. Additionally, a drug is considered adulterated if it purports to be a drug recognized in an official compendium, but fails to meet the quality or purity standards set forth in the compendium or the federal act. Va. Code §54.1-3461(B).

59. By manufacturing and selling an adulterated drug into the stream of Virginia commerce, the defendants violated Virginia Code §§ 54.1-3457(1), which is part of the Virginia Drug Control Act.

60. By negligently adulterating a drug, the defendants violated Virginia Code §§ 54.1-3457(2), which is part of the Virginia Drug Control Act.

61. By failing to adhere to proper quality control standards in producing the drug given to Mr. Wingate, the defendants failed to comply with USP-NF standards in violation of Virginia Code § 54.1-3410.2(E).

62. By engaging in the wholesale distribution of prescription drugs in this Commonwealth without a valid unrevoked license to do so issued by the Virginia Board of Pharmacy, the defendants violated Virginia Code § 54.1-3435, which is part of the Virginia Drug Control Act.



63. As pharmacist in charge, defendant Cadden was personally responsible for ensuring that NECC did not violate the provisions of the Virginia Drug Control Act. (Va. Code § 54.1-3432).

64. The defendants' actions violating Va. Code §§ 54.1-3457(1) and (2), 54.1-3410.2(E), and 54.1-3435 proximately caused Mr. Wingate's death. He died as a direct and proximate result of having the defendants' adulterated drug containing a fungal pathogen injected directly into his central nervous system.

65. Death or injury of a patient resulting from consumption of or contact with adulterated drugs belongs to the category of harms against which the Virginia Drug Control Act was designed to protect.

66. Death or injury of a patient resulting from consumption of or contact with adulterated drugs distributed wholesale by an entity engaging in the wholesale distribution of prescription drugs in this Commonwealth without registration belongs to the category of harms against which Virginia Drug Control Act was designed to protect

67. United States Code §§ 21 U.S.C. 301 *et seq.* (collectively known as "The Federal Food, Drug and Cosmetic Act" or "FDCA") are statutes enacted for public safety, in that they protect the public from the release of adulterated, substandard and otherwise unreasonably dangerous pharmaceutical drugs and medications into the stream of U.S. Commerce.

68. Therefore, because the defendants violated each of the above statutes, Virginia Code § 54.1-3457(1), Virginia Code § 54.1-3457(2) and Virginia Code § 54.1-3435), the defendants' actions and inactions constitute negligence *per se*, and the plaintiff is entitled to recovery of funeral, burial, and medical expenses, as well as damages for the statutory beneficiaries' extreme mental anguish,



sorrow, loss of companionship, comfort, guidance, kindly offices, invaluable services, and all other items of damage provided by the Virginia Death by Wrongful Act statutes.

**COUNT II: NEGLIGENT MANUFACTURE**

69. Plaintiff hereby incorporates each of the preceding paragraphs as if set forth fully herein.

70. The defendants owed a duty to Mr. Wingate, all other foreseeable users of their products, and the public in general to timely and properly:

- a. operate in a clean and sterile environment with properly functioning equipment;
- b. establish quality control measures;
- c. implement quality control measures;
- d. manufacture uncontaminated products;
- e. obtain representative sterility testing for their products for contamination prior to releasing the products into the stream of commerce; and
- f. refrain from releasing contaminated products into the stream of commerce;
- g. refrain from operating their facility in immediate proximity to a waste recycling center owned and operated by one of NECC's co-owners, and thus causing an inordinately high possibility that their drugs would become contaminated by contact with spores or other contaminants contained in the waste recycling center;
- h. refrain from producing such a high quantity of drugs that implementing proper quality control measures became difficult or impossible; and
- i. refrain from engaging in any other act or omission determined during the course of discovery.

71. The defendants breached the above duties and acted negligently, in at least the following ways, by failing to timely and properly:

- a. operate in a clean and sterile environment with properly functioning equipment;
- b. establish quality control measures;

- c. implement quality control measures;
- d. manufacture uncontaminated products;
- e. quality test their products for contamination prior to releasing the products into the stream of commerce;
- f. refrain from releasing contaminated products into the stream of commerce;
- g. refrain from operating their facility in immediate proximity to a waste recycling center owned and operated by one of NECC's co-owners, and thus causing an inordinately high possibility that their drugs would become contaminated by contact with spores or other contaminants contained in the waste recycling center;
- h. refrain from producing such a high quantity of drugs that implementing proper quality control measures became difficult or impossible; and
- i. refrain from engaging in any other act or omission determined during the course of discovery.

72. The product methylprednisolone acetate administered to Mr. Wingate was not reasonably safe at the time it left the defendants' control.

73. At the time the product left the control of the defendants, a feasible and reasonably implementable alternative production practice was available that would have prevented the harm caused to Mr. Wingate without significantly impairing the usefulness or desirability of the product and without creating equal or greater risk of harm to others.

74. Mr. Wingate's death occurred as a direct and proximate result of the defendants' breaches of their duties to Mr. Wingate listed above.

### **COUNT III: STRICT LIABILITY**

75. The plaintiff hereby incorporates each of the preceding paragraphs as if set out fully herein.

76. The defendants manufactured and sold a product that was inherently dangerous for any human use, particularly those involving introduction of the tainted drug into the central nervous system.

77. The inherently dangerous nature of the product was present at the time the product left the defendants' control.

78. Mr. Wingate's death was directly and proximately caused by the introduction of the defendants' inherently dangerous product into his body.

**COUNT IV: NEGLIGENT FAILURE TO WARN**

79. The plaintiff hereby incorporates each of the preceding paragraphs as if set forth fully herein.

80. The defendants were aware that NECC's production quantities exceeded amounts in which they could properly implement necessary quality controls.

81. The defendants knew or had reason to know that the drug given to Mr. Wingate was not produced under conditions that could reasonably ensure quality and sterility.

82. On information and belief, the defendants chose not obtain independent sterility test results from a representative sampling of the applicable batch of this drug from a third party sterility testing facility as other compounding pharmacies do before releasing such drugs. The size of the batches at issue made any such sampling (if done) representative of the thousands of dosages created.

83. The defendants knew or had reason to know that compounding medications surrounded by the owner's garbage recycling center would result in increased chances of contaminating such drugs before and during the manufacturing process. These circumstances, while unreasonable and unbelievable under any scenario, further heightened the need to adhere to

strict safety, quality, sterility and testing protocols. But, none of this was done. As a result, it was not a matter of “if” adulterated drugs would be produced and sold by NECC, but instead, a matter of when such would occur or when it would occur to such an extent that illness or death resulted. NECC was engaged in what amounted to “Russian-Roulette” with its practices.

84. Because of their knowledge of those issues, as well as other things, the defendants knew or had reason to know that their product, the methylprednisolone acetate, was dangerous for its intended uses.

85. The defendants had no reason to believe that Mr. Wingate would realize the dangerous condition of the methylprednisolone acetate.

86. Mr. Wingate could not possibly have contemplated or anticipated the dangerousness of the defendants’ product, as it was contained in a single, unremarkable dosage vial.

87. By engaging in the acts and omissions described above, and by failing to inform the buyers and foreseeable users of the contamination of the methylprednisolone acetate, the defendants failed to exercise reasonable care to inform users of the dangers associated with the product’s use.

#### **COUNT V: GROSS NEGLIGENCE**

88. The plaintiff hereby incorporates each of the preceding paragraphs as if set forth fully herein.

89. Each of the foregoing acts and omissions by the defendants went beyond mere thoughtlessness, inadvertence or error of judgment.

90. Such acts and omissions constituted such an utter disregard for the rights of others, and such an utter disregard for prudence, that they amount to complete neglect of the safety of others, including Mr. Wingate. The defendants’ acts and omissions were a heedless and palpable

violation of their legal duties respecting the life and rights of Mr. Wingate. Frazier v. City of Norfolk, 234 Va. 388, 393, 362 S.E.2d 688, 691 (1987).

91. Mr. Wingate's death occurred as a direct and proximate result of the defendants' grossly negligent acts and omissions.

**COUNT VI: BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

92. The plaintiff hereby incorporates each of the preceding paragraphs as if set forth fully herein.

93. The defendants had a duty to buyers and foreseeable users such as Mr. Wingate to provide a product that was not unreasonably dangerous for the use for which it was intended, and was not unreasonably dangerous for other foreseeable uses.

94. Despite that duty, the methylprednisolone acetate was unreasonably dangerous for the use for which it was intended—epidural injection into the bodies of patients, including Mr. Wingate—as well as other reasonably foreseeable uses.

95. The methylprednisolone acetate was unreasonably dangerous for the above-stated uses at the time the product left the defendants' hands.

96. The unreasonably dangerous condition of the methylprednisolone acetate directly and proximately caused Mr. Wingate's fungal meningitis and subsequent death.

**COUNT VII: BREACH OF IMPLIED  
WARRANTY OF USE FOR A PARTICULAR PURPOSE**

97. The plaintiff hereby incorporates each of the preceding paragraphs as if set forth fully herein.

98. The defendants have heavily marketed both NECC itself and the product methylprednisolone acetate at medical trade shows and the like for use in the pain management setting, including but not limited to inclusion in epidural injections for back pain relief.

99. The defendants knew or had reason to know that the intermediate buyer, Insight Imaging, planned to use the methylprednisolone acetate in administering epidural injections to patients.

100. As such, the defendants knew or had reason to know the particular purpose for which the methylprednisolone acetate was purchased.

101. The defendants had reason to know that their skill or judgment was being relied upon to provide appropriate and reasonably safe goods.

102. At the time of the sale, the methylprednisolone acetate failed to satisfy the purpose contemplated at the time of sale—to be injected into the central nervous systems of patients such as Mr. Wingate without causing those patients to suffer unanticipated and unreasonably unsafe side-effects, e.g., fungal meningitis and death.

103. The failure of the product to satisfy the purpose contemplated at the time of sale proximately caused Mr. Wingate's fungal meningitis and death.

**COUNT VIII: MEDICAL NEGLIGENCE**  
(defendant Cadden)

104. Plaintiff repeats and re-alleges all allegations contained in the preceding paragraphs as if they were fully set forth herein.

105. As director of pharmacy and licensed pharmacist in charge of NECC's operations, Cadden was at all relevant times acting as NECC's agent and / or principal.

106. Cadden had a duty to Mr. Wingate and other patients receiving these injections to utilize basic safety and cleanliness standards in the drug manufacturing processes.

107. Cadden had a duty to Mr. Wingate and other patients receiving these injections to exercise reasonable care to ensure that the drugs NECC manufactured were sterile and were not adulterated.

108. Cadden breached his duties to Mr. Wingate. He failed to utilize basic safety and cleanliness standards in the drug manufacturing processes, and he failed to exercise reasonable care to ensure that the drugs he and NECC manufactured were sterile and not adulterated.

109. Cadden's breaches of duty to Mr. Wingate proximately caused Mr. Wingate's death.

110. The plaintiff has incurred funeral, burial, and medical expenses, and Mr. Wingate's beneficiaries have suffered extreme mental anguish, sorrow, loss of companionship, comfort, guidance, kindly offices, invaluable services, and all other items of damage provided by the Virginia Death by Wrongful Act statutes, as a proximate result of NECC's and Cadden's breaches of the duties they owed to Mr. Wingate. Va. Code § 8.01-50, *et seq.*

111. The Plaintiff certifies that she has complied with Va. Code § 8.01-50.1 before requesting service of process.

WHEREFORE, Sharon G. Wingate, Executor of the Estate of Douglas Gray Wingate, deceased, by counsel, moves this Court for judgment against the defendants, jointly and severally, in the amount of \$25,000,000 plus taxable costs with pre- and post-verdict interest on all of these amounts, as well as \$350,000 in punitive damages.

**PLAINTIFF REQUESTS A TRIAL BY JURY ON ALL ISSUES.**

SHARON G. WINGATE, EXECUTOR OF THE  
ESTATE OF DOUGLAS GRAY WINGATE,  
DECEASED,

/s/ J. Scott Sexton

By Counsel



J. Scott Sexton, Esq. (VSB No. 29284)  
Anthony M. Russell (VSB No. 44505)  
Charles H. Smith, III (VSB No. 32891)  
Benjamin D. Byrd (VSB No. 76560)  
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*Counsel for Sharon G. Wingate, Executor of the  
Estate of Douglas Gray Wingate, deceased*





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EXHIBIT A



JS 44 (Rev. 12/07)

## CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

## I. (a) PLAINTIFFS

Sharon G. Wingate, Executor of The Estate of Douglas Gray Wingate, deceased

(b) County of Residence of First Listed Plaintiff Salem  
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)  
J. Scott Sexton, Esq. / Gentry Locke Rakes & Moore, LLP  
10 Franklin Road, SE, Suite 800, Roanoke, VA 24011 / 540-983-9300

## DEFENDANTS

New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center, Medical Sales Management, Inc., Barry J. Cadden

County of Residence of First Listed Defendant \_\_\_\_\_  
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

## II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff  
☐ 2 U.S. Government Defendant  
☐ 3 Federal Question (U.S. Government Not a Party)  
☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

## III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- |   | PTF                                   | DEF                                   |   | PTF                        | DEF                                   |
|---|---------------------------------------|---------------------------------------|---|----------------------------|---------------------------------------|
| Citizen of This State                   | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 1            | Incorporated or Principal Place of Business in This State     | <input type="checkbox"/> 4 | <input type="checkbox"/> 4            |
| Citizen of Another State                | <input type="checkbox"/> 2            | <input checked="" type="checkbox"/> 2 | Incorporated and Principal Place of Business in Another State | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3            | <input type="checkbox"/> 3            | Foreign Nation  | <input type="checkbox"/> 6 | <input type="checkbox"/> 6            |

## IV. NATURE OF SUIT (Place an "X" in One Box Only)

<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury	<b>PERSONAL INJURY</b> <input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input checked="" type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act <b>IMMIGRATION</b> <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 463 Habeas Corpus - Alien Detainee <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>PROPER RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark <b>LABOR</b> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes
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## V. ORIGIN

- (Place an "X" in One Box Only)
- ☒ 1 Original Proceeding  
☐ 2 Removed from State Court  
☐ 3 Remanded from Appellate Court  
☐ 4 Reinstated or Reopened  
☐ 5 Transferred from another district (specify)  
☐ 6 Multidistrict Litigation  
☐ 7 Appeal to District Judge from Magistrate Judgment

## VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

28 U.S.C. 1332(a) - Diversity

Brief description of cause:

Wrongful death caused by tainted steroid

## VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23  
DEMAND \$ 25,000,000.00

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

## VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE \_\_\_\_\_

DOCKET NUMBER \_\_\_\_\_

DATE

11-20-12

SIGNATURE OF ATTORNEY OF RECORD

*J. Scott Sexton*

FOR OFFICE USE ONLY

RECEIPT #

0423-1463177

AMOUNT

350.00

APPLYING IFP

JUDGE

Wilson

MAG. JUDGE

7:12-CV-00576

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF VIRGINIA  
ROANOKE DIVISION

SHARON G. WINGATE, EXECUTOR OF )  
THE ESTATE OF DOUGLAS GRAY )  
WINGATE, DECEASED, )

Plaintiff, )

v. )

CIVIL ACTION NO.: 7:12-cv-00576

NEW ENGLAND COMPOUNDING )  
PHARMACY, INC. D/B/A NEW )  
ENGLAND COMPOUNDING CENTER, )

MEDICAL SALES MANAGEMENT, )  
INC., )

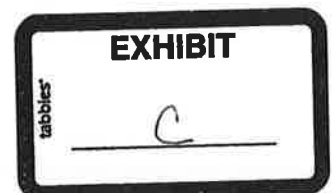
and )

BARRY J. CADDEN, )

Defendants. )

**NOTICE OF STAY BY REASON OF BANKRUPTCY**

The defendant, New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC"), hereby notifies the Court that NECC filed a voluntary petition under Chapter 11 of Title 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Massachusetts (Eastern Division) No. 12-19882-HJB. Pursuant to 11 U.S.C. § 362(a) all actions against NECC are stayed.



Respectfully submitted,  
Defendant New England Compounding Pharmacy, Inc.  
By its Attorneys,

/s/

---

Rebecca S. Herbig  
Bowman and Brooke LLP  
1111 East Main Street, Suite 2100  
Richmond, VA 23219  
Telephone: 804.649.8200  
Facsimile: 804.649.1762  
E-mail: rebecca.herbig@bowmanandbrooke.com

Date: December 26, 2012

## CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of foregoing Notice of Stay by Reason of Bankruptcy was filed via CM/ECF on this 26<sup>th</sup> day of December, 2012, which will send a Notice of Electronic Filing (NEF) to the following:

J. Scott Sexton (VSB No. 29284)  
Anthony M. Russell (VSB No. 44505)  
Charles H. Smith, III (VSB No. 32891)  
Benjamin D. Byrd (VSB No. 76560)  
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*Counsel for Plaintiff*

/s/

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*Counsel for New England Compounding  
Pharmacy, Inc., d/b/a New England  
Compounding Center*

VIRGINIA

IN THE CIRCUIT COURT FOR THE CITY OF ROANOKE

SHARON G. WINGATE,  
EXECUTOR OF THE ESTATE OF  
DOUGLAS GRAY WINGATE, DECEASED

Plaintiff,

v.

INSIGHT HEALTH CORP.,  
JOHN MATHIS, M.D.,  
ROBERT F. O'BRIEN, M.D.,  
And  
IMAGE GUIDED PAIN MANAGEMENT,  
P.C.

Defendants.

Case No. CL12-2547

**DEMURRER OF INSIGHT HEALTH CORP.**

COMES NOW, Defendant INSIGHT HEALTH CORP. ("IHC"), by and through counsel, Bonner Kiernan Trebach & Crociata, LLP, and as its Demurrer to the Plaintiff's Complaint states as follows:

**DEMURRER AS TO ALL COUNTS**

Plaintiff has omitted the manufacturer of the alleged contaminated steroids at issue in this case, NEW ENGLAND COMPOUNDING CENTER a/k/a NEW ENGLAND COMPOUNDING PHARMACY ("NECC") from this action. In its absence, among other things, "complete relief cannot be accorded among those already parties." Va. Sup. Ct. R. 3:12(a). Accordingly, NECC is a necessary and indispensable party to this action. Va. Sup. Ct. R. 3:12 (a) and (c); *Asch v. Friends of Mt. Vernon Yacht Club*, 251 Va. 89, 90 (1996) (a court lacks the power to proceed with a suit unless all necessary parties are properly before the court and, if not, the matter must be dismissed); *Gray v. Virginia Secretary of*

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*Transportation*, 77 Va. Cir. 224, 227-228 (Cir. Ct. City of Richmond, 2008) (discussing Va. Sup. Ct. R. 3:12 (a) and (c) and dismissing action because necessary and indispensable party not in the action) (citing *Mendenhall v. Cooper*, 239 Va. 71, 74 (1990) (failure to join necessary and indispensable party mandates dismissal of action)). Accordingly, Plaintiff's claims against IHC must fail.

#### **DEMURRER AS TO COUNT I – NEGLIGENCE *PER SE***

In Count I, Plaintiff contends that IHC is negligent *per se* based on a violation of various sections of Va. Code § 54.1-3400, known as the Virginia Drug Control Act ("VDCA"), including Va. Code § 54.1-3461(A)(2) (preparation or release of unsanitary drugs), Va. Code § 54.1-3461(B) (failing to meet purity or quality standards in drug compendium or under federal standard), and 54.1-3457 (1) and (3) (release of impure drug into commerce and injuring patients). (Complaint ¶¶ 181-194.) However, the sections of the VDCA relied upon by Plaintiff do not apply to IHC because they apply only to pharmacists, and not to health care providers or other parties involved in the health care process. *See* Va. Code. § 54.1-3410.2(D) (it is the pharmacist, and not the treating or administering health care provider or other party involved in that process, who "shall personally perform or ... supervise the compounding process, which shall include a final check for accuracy and conformity to the formula of the product ... appropriate conditions and procedures, and appearance of the final product"), and Va. Code. § 54.1-3410.2(E) (it is only the pharmacist who "shall ensure compliance with the USP-NF standards for ... sterile ... compounding."). Moreover, there is no stand-alone or separate cause of action for negligence *per se* under Virginia law; rather, any such claim must arise from a breach of a standard of care set forth by statute. *See Williams v. Old Brogue, Inc.*, 232 Va. 350 (1986) (the doctrine of negligence *per*

se does not exist as a stand alone claim and cannot create a cause of action where none otherwise exists); *Talley v. Danek Med., Inc.*, 179 F.3d 154, 158 (4<sup>th</sup> Cir. 1999) (“the negligence per se doctrine, however, is not a magic transforming formula that automatically creates a private right of action for the civil enforcement, in tort law, of every statute.”). Accordingly, because the VDCA does not apply to IHC, and there can be no stand-alone claim for negligence *per se* under Virginia law, Plaintiff’s negligence *per se* claim against IHC must fail.

#### **DEMURRER AS TO COUNT II – VIRGINIA CONSUMER PROTECTION ACT**

In Count II, Plaintiff alleges that the decedent and IHC engaged in a transaction involving the sale of the steroid that falls under the purview of Va. Code § 59.1-198, the Virginia Consumer Protection Act (“VCPA”). Hence, Plaintiff contends that IHC is a “supplier in connection with a consumer transaction” as those terms are defined under the VCPA. However, IHC is neither a “supplier” nor was there a “consumer transaction” for the “sale of goods” such that the VCPA could apply. *See* Va. Code § 59.1-198 (a “‘supplier’ is defined as a seller, lessor or licensor who advertises, solicits or engages in consumer transactions.”); (“‘[c]onsumer transaction’ [is] the advertisement, sale, lease, license or offering for sale, lease or license, of goods or services to be used primarily for personal, family or household purposes.”); *Coffman v. Anthrex, Inc., et al.*, 69 Va. Cir. 17, 18-19 (Cir. Ct. Augusta Cty. 2005) (product liability claim involving defective medical device dismissed because a health care provider cannot be a “seller” under the Virginia Commercial Code in that context and there can be no “sale” because any such transaction was incidental to the rendering of healthcare services); *Wachovia Bank, N.A. v. Bourn*, 2003 U.S. Dist. LEXIS 519, \*8-\*9, Civ. No. 7:02CV00773, (W.D. Va. Jan. 7, 2003) (there must be a “transfer of title” to

the good in order for there to be a “sale.”). Accordingly, Plaintiff’s claim under the VCPA against IHC must fail.

### **DEMURRER AS TO COUNT III – NEGLIGENCE**

The Complaint fails to allege sufficient facts to demonstrate that IHC owed a duty to the Plaintiff. The Complaint alleges that the decedent received an epidural steroid injection at “Insight Imaging-Roanoke.” (Complaint ¶158.) The Complaint further alleges that the epidural steroid injection was administered by Dr. O’Brien, an employee of “Insight Imaging-Roanoke.” (*Id.* ¶¶ 41, 42, 159). The Court may take judicial notice of the fact that the fictitious name “Insight Imagining-Roanoke” is registered to Image Guided Pain Management, P.C. *See* Va. Code §§8.01-388 and 389; *see also* *Station #2, LLC v. Lynch*, 75 Va. Cir. 179, 191 (Cir. Ct. City of Norfolk, April 2008) (the court may take judicial notice of public records); *Slaughter v. Commonwealth*, 54 Va. 767, 777 (1856) (“the court would take judicial notice of private corporations created under general law, whose certificates were printed with the public acts of the Legislature ....”); *see also* Virginia State Corporation Commission filing for SCCID#07221021 for Insight-Imaging Roanoke attached as Exhibit A. Accordingly, while Plaintiff’s Complaint alleges that a doctor-patient relationship existed between Image Guided Pain Management/Dr. O’Brien and the decedent, it fails to allege there was any such relationship between the decedent and IHC. Thus, the Plaintiff’s Complaint fails to allege any facts that would support a contention that there was a duty owed by IHC to the decedent.

### **DEMURRER AS TO COUNT IV - GROSS NEGLIGENCE**

In Count IV, Plaintiff alleges a claim for Gross Negligence. This claim must similarly fail because, just like the Negligence Count, the allegations contained in Plaintiff’s Complaint

do not allege specific facts that would support a contention that there was a duty owed by IHC to the decedent to support a claim for gross negligence. See *Frazier v. City of Norfolk*, 234 Va. 388, 393 (1987); *Kennedy v. McElroy*, 195 Va. 1078, 1082, 81 S.E.2d 436, 439 (1954); (Complaint ¶¶23-49). Moreover, it is simply not enough to merely recite the elements of the cause of action that all defendants, for instance, were “heedless and palpable,” or all acted with “such an utter disregard for prudence.” (Complaint ¶¶ 217-221.) Instead, Plaintiff must plead specific facts as to IHC. See *BB&T Ins. Servs. v. Thomas Rutherford, Inc.*, 80 Va. Cir. 174, 176 (Cir. Ct. City of Richmond, Feb. 9, 2010) (formulaic recitation of the elements of a cause of action, instead of pleading actual facts, will not suffice and the court granted the demurrer as to a claim for breach of fiduciary duty). Therefore, Plaintiff’s claim for gross negligence must fail.

#### **COUNT V – FRAUD**

In Count V, Plaintiff alleges Fraud. This, too, must fail because the allegations in Plaintiff’s Complaint do not allege specific facts that would support a contention that, for example, there was a false representation made intentionally and knowingly by IHC, or with intent to mislead, or that there was reliance on any such purported misrepresentation. See, e.g., *State Farm Mut. Auto. Ins. Co. v. Remley*, 270 Va. 209, 218, 618 S.E.2d 316, 321 (2005). There are neither specific allegations that IHC made a representation of any kind, intentionally or otherwise, regarding the steroids at issue to the decedent nor that the decedent relied on any such purported representation allegedly made by IHC. (Complaint ¶¶223-251, wherein all allegations are against “Insight-Imaging-Roanoke” and not against IHC); see *Mortarino v. Consultant Engineering Services*, 251 Va. 289, 295 (1999) (demurrer as to fraud count affirmed because the pleadings did not set forth specific allegations that a representation

had been made to the plaintiff and that the defendant "knew or had reason to know" that the plaintiff would rely upon any such representation); *see also BB&T*, 80 Va. Cir. at 176 (formulaic recitation of the elements of a cause of action, instead of actual facts plead, will not suffice and the court granted the demurrer); *Station #2*, 75 Va. Cir. at 194 (granting demurrer as to the fraud count because plaintiff failed to allege misrepresentation made to, and relied upon by, plaintiff.) Accordingly, Plaintiff's fraud claim against IHC must fail.

#### **DEMURRER AS TO PUNITIVE DAMAGES**

Plaintiff's Complaint also seeks punitive damages against IHC. However, the Complaint fails to allege any facts against IHC that could support a claim for punitive damages; specifically, Plaintiff has failed to allege facts which would support a conclusion that IHC acted with malice or in willful and wanton disregard to Plaintiff's rights. *See, e.g., Xsepedius Management Co. of Virginia, LLC v. Stephan*, 269 Va. 421, 425 (2005); *Hogg v. Plant* 145 Va. 175 (1926). Accordingly, Plaintiff's claim for punitive damages against IHC must fail.

WHEREFORE, for the reasons stated above and in the Memorandum of Law which Defendant IHC shall supply to the Court before the hearing on it is Demurrer, Defendant IHC prays this Court will sustain its Demurrer, and that the Motion for Judgment against IHC be dismissed with prejudice and that IHC be awarded its costs of this action together with whatever further relief this Court may deem just and proper.

Date: January 24, 2013

**BONNER KIERNAN TREBACH & CROCIATA,  
LLP**



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Christopher E. Hassell, Esquire VSB#30469

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***Counsel for Insight Health Corp.***



**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY, that I caused to be served the foregoing Demurrer of INSIGHT HEALTH CORP. via regular mail and email this 24<sup>th</sup> day of January, 2013 to:


J. Scott Sexton  
Gentry Locke Rakes & Moore, LLP  
10 Franklin Road, S.E., Suite 800  
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Christopher E. Hassell  
Brian J. Gerling

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<a href="#">F1582438</a>	<a href="#">INSIGHT IMAGING(ARLINGTON CO)</a>	Foreign Corporation	Fictitious name
<a href="#">F1582438</a>	<a href="#">INSIGHT IMAGING CENTER OF ARLINGTON(ARLINGTON CO)</a>	Foreign Corporation	Fictitious name
<a href="#">F1582438</a>	<a href="#">INSIGHT IMAGING - FAIRFAX(FAIRFAX CO)</a>	Foreign Corporation	Fictitious name
<a href="#">S1725367</a>	<a href="#">INSIGHT IMAGING, L.L.C.</a>	Limited Liability Company	Canceled
<a href="#">T0482994</a>	<a href="#">INSIGHT IMAGING, LLC</a>	Foreign Limited Liability Company	Active
<a href="#">07221021</a>	<a href="#">INSIGHT IMAGING - ROANOKE(ROANOKE CI)</a>	Corporation	Fictitious name
<a href="#">F1582438</a>	<a href="#">INSIGHT IMAGING - WOODBRIDGE(PRINCE WILLIAM CO)</a>	Foreign Corporation	Fictitious name
<a href="#">F1582438</a>	<a href="#">INSIGHT IMAGING - WOODBRIDGE(PRINCE WILLIAM CO)</a>	Foreign Corporation	Fictitious name
<a href="#">01850494</a>	<a href="#">INSIGHT INCORPORATED</a>	Corporation	Active

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


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**Image Guided Pain Management, P.C.**

**General**

SCC ID: 07221021  
Entity Type: Corporation  
Jurisdiction of Formation: VA  
Date of Formation/Registration: 4/19/2010  
Status: Active  
Shares Authorized: 5000

**Principal Office**

2923 FRANKLIN ROAD SW  
ROANOKE VA24014

**Registered Agent/Registered Office**

HERMAN A MARSHALL III  
10 S JEFFERSON ST  
STE 1400  
ROANOKE VA 24011  
ROANOKE CITY 217  
Status: Active  
Effective Date: 4/19/2010

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**VIRGINIA:**

**IN THE CIRCUIT COURT FOR THE CITY OF ROANOKE**

**SHARON G. WINGATE, Executor of the Estate of** )  
**Douglas Gray Wingate, Deceased,** )

Plaintiff, )

v. )

Case No. CL 12-2547

**INSIGHT HEALTH CORP.;** )

**DEMURRERS, PLEAS IN BAR,**  
**ANSWER, CROSS-CLAIMS**

Defendant/Cross-Claim Defendant, )

v. )

**JOHN M. MATHIS, M.D.; ROBERT F. O'BRIEN,** )  
**M.D.; and IMAGE GUIDED PAIN** )  
**MANAGEMENT, P.C.,** )

Defendants/Cross-Claim Plaintiffs. )

**PLEA IN BAR TO COMPLAINT**

COME NOW defendants John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. (collectively "IGPM"), by counsel and move the Court to refuse to exercise jurisdiction because New England Compounding Pharmacy, Inc d/b/a New England Compounding Center (NECC) is a necessary and indispensable party and cannot be included in this litigation and states as follows in support:

1. NECC is a Massachusetts entity engaged in the business of managing and operating a pharmacy and providing pharmacy services, including but not limited to designing, manufacturing, compounding, testing, marketing, distributing, selling and introducing into interstate commerce, including within the Commonwealth of Virginia, drugs and pharmaceuticals, including methylprednisolone acetate.



2. NECC marketed to, contracted with, sold to and delivered to Insight Health Corp. ("Insight") sealed vials of methylprednisolone acetate for use as an injectable steroid at Insight Health Corp.'s 2923 Franklin Road, S.W. Roanoke, Virginia 24014 location ("Roanoke location").

3. NECC manufactured and/or compounded the methylprednisolone acetate at its Framingham, Massachusetts facility where investigators from the U.S. Food and Drug Administration ("FDA") and the Massachusetts Department of Public Health ("DPH") found unclean and insterile conditions, including but not limited to mold, fungus, bacteria, dirty air ducts, dirty ventilation systems, soiled floor coverings, and a leaking boiler surrounded by a pool of water, in or around the locations where the methylprednisolone acetate was being compounded.

4. NECC distributed methylprednisolone acetate prior to receiving results of sterility testing on the distributed methylprednisolone acetate.

5. NECC failed to follow autoclaving sterilization procedures for the required minimum 20-minute sterilization period necessary to ensure product sterility.

6. The sealed vials of methylprednisolone acetate that NECC distributed to purchasers, including Insight, allegedly contained a black particulate matter later identified as a fungus.

7. Without knowledge of the unclean, unsterile conditions of the NECC facility and of NECC's compounding practices and without knowledge of the alleged condition of the methylprednisolone acetate, IGPM injected into the spinal canals of patients, including Douglas Wingate, the methylprednisolone acetate from the sealed vials NECC sold to Insight.

8. The Estate of Douglas Wingate is pursuing negligence claims against IGPM regarding the alleged condition of the methylprednisolone acetate about which IGPM had no knowledge. These claims are part of the combined relief sought of \$25 million, plus costs, fees, interest, treble damages and punitive damages.

9. NECC has filed for Chapter 11 bankruptcy and has named IGPM as a creditor, preventing IGPM from filing a third-party complaint in this matter against NECC.

10. NECC has not been included in this matter as a defendant and is a necessary party, as complete relief cannot be accorded among those already parties for the negligence, negligence *per se* and gross negligence counts contained in the Complaint.

11. NECC has an interest to protect in this litigation, which is indicated by having identified IGPM as a creditor in bankruptcy, but NECC cannot protect that interest without being named a party, which cannot occur as a result of the bankruptcy filing.

12. NECC cannot be made a party and is indispensable because IGPM cannot bring in NECC in a third party complaint to answer for the negligence claims, because no relief can take into account NECC's negligence and because there can be no recovery if NECC's negligence is not also taken into account. Were it not for NECC's negligence of which IGPM was unaware, there would have been no injury.

13. Complete justice cannot be accomplished without NECC as a party to this litigation.

WHEREFORE, because an indispensable party cannot be included as a defendant in this matter, John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. respectfully request the Court to dismiss the Complaint.



## **DEMURRERS TO COUNT II**

COME NOW defendants John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. (collectively "IGPM"), by counsel and demur to Count II of the Complaint for the following reasons:

1. Count II sets forth claims of violation of the Virginia Consumer Protection Act by virtue of a consumer transaction consisting of the supply and sale of methylprednisolone acetate for use as an injectable steroid. VA CODE § 59.1-200.

2. The Virginia Consumer Protection Act excludes from its provisions any aspect of a consumer transaction which aspect is authorized under laws or regulations of the Commonwealth of Virginia and of the United States. VA CODE § 59.1-199. The formulation, compounding and sale of drugs is authorized under the Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§ 301, *et. seq.*; regulated by the U.S. Food and Drug Administration, 21 C.F.R. §§200, *et. seq.*; and authorized by the Virginia Drug Control Act, §§54.1-3400, *et seq.*

3. In Count II, plaintiff seeks recovery for damages provided by the Virginia Wrongful Death Act statutes, which are not available under the Virginia Consumer Protection Act, which provides for economic damages only.

WHEREFORE, Count II fails to state claims upon which relief can be granted and John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. respectfully request the Court to dismiss Count II.

#### **DEMURRER TO COUNT IV**

COME NOW defendants John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. (collectively "IGPM"), by counsel and demur to Count IV of the Complaint for the following reasons:

1. In plaintiff's Count IV for gross negligence, plaintiff cites no specific facts that constitute gross negligence, but makes merely conclusory allegations.
2. Plaintiff's conclusory allegations of gross negligence constitute actions or omissions by NECC and not by IGPM.
3. Plaintiff's only quasi-factual allegation is that IGPM did not ensure that it was not injecting adulterated drugs into its patients, which IGPM could not do without opening the sealed vials and tainting the drug.

WHEREFORE, Count IV fails to state claims or facts upon which the relief demanded can be granted and John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. respectfully request the Court to dismiss Count IV.

#### **DEMURRER TO COUNT V**

COME NOW defendants John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. (collectively "IGPM"), by counsel and demur to Count V of the Complaint for the following reasons:

1. Count V sets forth claims of actual and constructive fraud.
2. For an actual fraud claim, plaintiff must set forth facts that defendants made a false representation of a material fact, intentionally and knowingly with intent to mislead or that defendants knowingly and deliberately did not disclose material facts. Plaintiff

must also assert that he relied on the false representation and that reliance led to damages or injury. For constructive fraud, the false representation must be made innocently or negligently.

3. Plaintiff asserts that misinformation on the name of the medication was a material misrepresentation of fact upon which Mr. Wingate relied as to the safety of the drug. In essence, plaintiff asserts that by the very name of the medication, Mr. Wingate knew it to be safe and was induced into proceeding with the steroid injections. Plaintiff does not assert that IGPM informed Mr. Wingate that the name-brand drug was safe.

4. Plaintiff does not allege that Mr. Wingate was advised of the name of the drug prior to consenting to the procedure, and, thus, cannot state that Mr. Wingate relied on the alleged information provided.

5. Plaintiff further asserts that a misrepresentation to a third party, Mr. Wingate's insurance carrier, was a fraud perpetrated on Mr. Wingate because the insurer relied on that information to Mr. Wingate's detriment. This is not a fraud claim. Plaintiff must claim that the misrepresentation was made to him and he relied on it and was injured. Plaintiff cannot claim that he was injured by a third party's reliance on a misrepresentation. Further, Plaintiff cannot claim that Mr. Wingate relied on information provided for billing purposes because such alleged misrepresentations occurred after Mr. Wingate consented to the procedure and, thus, after he would have had the opportunity to rely on such billing information.

WHEREFORE, Count V fails to state claims or facts upon which the relief demanded can be granted and John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. respectfully request the Court to dismiss Count V.

**DEMURRER ON PUNITIVE DAMAGES CLAIM**

COME NOW defendants John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. (collectively "IGPM"), by counsel and demur to plaintiff's punitive damages request for the following reasons:

1. Plaintiff has set forth no allegations of willful and wanton conduct on the part of IGPM.
2. Plaintiff has failed to assert that IGPM acted recklessly in a manner that amounted to willful and wanton disregard to Douglas Wingate's rights.
3. Plaintiff has failed to assert facts that indicate IGPM engaged in conduct that was taken in conscious disregard of Mr. Wingate's rights or with reckless indifference to consequences that IGPM was aware, from its knowledge of existing circumstances and conditions, would probably result from its conduct and cause injury to Mr. Wingate.

WHEREFOR, the Complaint fails to set forth facts sufficient to warrant an award of punitive damages and John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. respectfully request the Court to dismiss plaintiff's claim for punitive damages.

**PLEA IN BAR TO COUNT I**

COME NOW defendants John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. (collectively "IGPM"), by counsel and move the Court to dismiss Count I of the Complaint as to them for the following reasons:

1. Count I sets forth claims of negligence *per se* for violation of the Virginia Drug Control Act.

2. For its claims, Count I relies on the prohibition in the Virginia Drug Control Act against the manufacture, sale, delivery, holding, offering for sale or receipt in commerce of adulterated drugs. VA CODE § 54.1-3457.

3. Count I does not set forth a viable claim against IGPM because IGPM did not manufacture, sell, deliver, hold, offer for sale or receive in commerce adulterated drugs, but merely provided the service, as interventional radiologists, of injecting the medication.

WHEREFORE, Count I fails to state a cause of action against John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. for negligence per se and John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. respectfully request the Court to dismiss Count I as to them.

### **PLEA IN BAR TO COUNT II**

COME NOW defendants John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. (collectively "IGPM"), by counsel and move the Court to dismiss Count II of the Complaint as to them for the following reasons:

1. Count II sets forth claims of violation of the Virginia Consumer Protection Act by virtue of a consumer transaction consisting of the supply and sale of methylprednisolone acetate misrepresented as Depo-Medrol. VA CODE § 59.1-200.

2. Count II fails to state a cause of action against IGPM because IGPM did not engage in the sale of the medication to the plaintiff's deceased, but merely provided the service, as interventional radiologists, of injecting the medication.

WHEREFORE, Count II fails to state a cause of action against John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. for violation of the Virginia Consumer Protection Act and John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. respectfully request the Court to dismiss Count II as to them.

**PLEA IN BAR TO COUNT III**

COME NOW defendants John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. (collectively "IGPM"), by counsel and move the Court to dismiss Count III of the Complaint as to them for the following reasons:

1. Count III sets forth claims that IGPM had a duty to ensure that the drugs supplied to IGPM and the manufacturer of those drugs were in compliance with federal and state laws and that IGPM breached that duty.

2. IGPM provided interventional radiology services only to Mr. Wingate, and any claims of negligence on the part of IGPM are governed by the Virginia Medical Malpractice Act, §§ 8.01-581.1 *et seq.* and must be accompanied by assertions of medical negligence.

3. Count III fails to assert that IGPM violated the standard of care for interventional radiologists practicing in the Commonwealth of Virginia and, thus, fails to assert a viable negligence claim against IGPM.

WHEREFORE, Count III fails to state a cause of action against John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. for negligence and John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. respectfully request the Court to dismiss Count III as to them.



**PLEA IN BAR TO COUNT IV**

COME NOW defendants John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. (collectively "IGPM"), by counsel and move the Court to dismiss Count IV of the Complaint as to them for the following reasons:

1. Count IV sets forth claims that IGPM had a duty to ensure that the drugs supplied to IGPM and the manufacturer of those drugs were in compliance with federal and state laws and was grossly negligent in failing to do so.

2. IGPM provided interventional radiology services only to Mr. Wingate, and any claims of gross negligence on the part of IGPM are governed by the Virginia Medical Malpractice Act, §§ 8.01-581.1 *et seq.* and must be accompanied by assertions of medical negligence.

3. Count IV fails to assert that IGPM violated the standard of care for interventional radiologists practicing in the Commonwealth of Virginia and, thus, fails to assert a viable gross negligence claim against IGPM.

WHEREFORE, Count IV fails to state a cause of action against John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. for gross negligence and John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. respectfully request the Court to dismiss Count IV as to them.

**PLEAS IN BAR TO COUNT V**

COME NOW defendants John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. (collectively "IGPM"), by counsel and move the Court to dismiss Count V of the Complaint as to them for the following reasons:

1. Count V sets forth claims of fraud, asserting that the defendants knew and did not inform Mr. Wingate that the methylprednisolone acetate was produced at a compounding pharmacy with the characteristics identified in the Complaint, that the defendants falsely identified the drug as Depo-Medrol, and that the defendants falsely coded and billed the drug as a generic version of Depo-Medrol to avoid payment problems with Mr. Wingate's medical insurance provider.

2. Count V fails to state a cause of action against IGPM because IGPM did not engage in the purchase of the medication from the compounding pharmacy, did not sell the medication to Mr. Wingate and did not bill Mr. Wingate or his insurer for the medication, but merely provided the service, as interventional radiologists, of injecting the medication.

3. Count V also fails to state a cause of action for constructive fraud against IGPM for failure to inform Mr. Wingate that the methylprednisolone acetate was produced at a compounding pharmacy with the characteristics identified in the Complaint because IGPM did not have a duty to inform Mr. Wingate of those facts.

WHEREFORE, Count V fails to state a cause of action against John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. for fraud and John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. respectfully request the Court to dismiss Count V as to them.

**ANSWER**

COME NOW defendants John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C. (collectively "IGPM"), by counsel, and state that their responses to the Complaint allegations do not constitute responses for Insight



as Insight Imaging-Roanoke because Insight Imaging is a subsidiary of Insight Health Corp. and IGPM is a medical practice consisting of two radiologists.

6. IGPM admits the allegations contained in paragraph 12 of the Complaint with regard to the selection, procurement and preparation of drugs it administered and is without knowledge as to the selection, procurement and preparation of drugs administered by any other entity and thus denies those allegations and demands strict proof thereof.

7. IGPM denies the allegations contained in paragraphs 27, 28, 45, 58, 59, 60, 61, 62, 63, 64, 73, 77, 78, 80, 83, 85, 88, 90, 91, 92, 93, 94, 96, 97, 99, 100, 107, 110, 115, 116, 117, 118, 119, 120, 121, 131, 132, 134, 136, 139, 140, 149, 151, 160, 178, 179, 189, 190, 194, 197, 198, 199, 200, 201, 202, 204, 205, 206, 207, 208, 209, 210, 213, 214(including all of its subparts), 215, 216, 218, 219, 220, 221, 222, 225, 226, 227, 228, 229, 231, 232, 233, 234, 235, 236, 237, 238, 242, 243, 244, 246, 247, 248, 249, 250, 251, and 252 of the Complaint as they pertain to IGPM and is without knowledge to form a belief as to the truth of the allegations as to Insight Health Corp. and, thus, deny those allegations and demand strict proof thereof.

8. IGPM admits the allegations contained in paragraphs 29, 30 and 31 to the extent that any entity other than Image Guided Pain Management, P.C. identified Dr. Mathis as medical director and denies those allegations to the extent that they assert that Image Guided Pain Management, P.C. identified Dr. Mathis as medical director.

9. IGPM denies the allegations contained in paragraph 37 of the Complaint to the extent that they indicate Dr. Mathis was an employee or agent of any entity other than Image Guided Pain Management, P.C. and admits the allegations to the extent that they

indicate that Dr. Mathis was an employee or agent of Image Guided Pain Management, P.C.

10. IGPM admits the allegations contained in paragraph 38 that Insight Imaging-Roanoke acted through its employees and agents, admits the remaining allegations in paragraph 38 to the extent that they assert that Dr. Mathis was an employee or agent of Image Guided Pain Management, P.C. and denies the remaining allegations to the extent that they assert that Dr. Mathis was an employee or agent of any entity other than Image Guided Pain Management, P.C.

11. IGPM cannot admit or deny the statements contained in paragraphs 39, 44, 46, 49, 50, 51, 52, 54, 81, 84, 87, 113, 182, 183, 186, 187, 188, 196, and 253 because they are statements of law and not statements of fact, and to the extent that a response is required, IGPM denies those allegations and demands strict proof thereof.

12. IGPM denies the allegations contained in paragraph 42 of the Complaint to the extent that they indicate Dr. O'Brien was an employee or agent of any entity other than Image Guided Pain Management, P.C. and admits the allegations to the extent that they indicate that Dr. O'Brien was an employee or agent of Image Guided Pain Management, P.C.

13. IGPM admits the allegations contained in paragraph 43 that Insight Imaging-Roanoke acted through its employees and agents, admits the remaining allegations in paragraph 43 to the extent that they assert that Dr. O'Brien was an employee or agent of Image Guided Pain Management, P.C. and denies the remaining allegations to the extent that they assert that Dr. O'Brien was an employee or agent of any entity other than Image Guided Pain Management, P.C.

14. IGPM admits the allegations contained in paragraphs 53 and 56 of the Complaint as they apply to IGPM and is without knowledge as to the truth of the allegations as they apply to Insight Health Corp.

15. IGPM admits the allegations contained in paragraph 123 of the Complaint that at the times and places pertinent to this action Drs. Mathis and O'Brien and Image Guided Pain Management did not know that Insight Health Corp. and its employees and agents were purchasing methylprednisolone acetate from NECC.

16. IGPM admits the allegations contained in paragraph 129 of the Complaint that Drs. Mathis and O'Brien and Image Guided Pain Management, through Drs. Mathis and O'Brien, were deprived from making informed and reasonable patient care decisions based on the information and lack of information provided about the methylprednisolone acetate.

17. IGPM admits the allegations contained in paragraph 130 of the Complaint that Drs. Mathis and O'Brien and Image Guided Pain Management, through Drs. Mathis and O'Brien, were deprived of information about the methylprednisolone acetate; denies that Image Guided Pain Management, P.C. failed to provide information it did not have to patients about the methylprednisolone acetate; and is without knowledge as to the remaining allegations contained in paragraph 130 and thus denies those allegations and demands strict proof thereof.

18. IGPM denies the allegations contained in paragraph 144 of the Complaint that Dr. O'Brien's medical documentation indicated that the medication injected into Mr. Wingate's spinal canal was a drug produced by Pfizer and admits that Dr. O'Brien



recorded in the medical records the name Depo-Medrol in a generic sense, referring to steroids.

19. IGPM cannot admit or deny the statements made in paragraphs 180 and 254 of the Complaint, as they are not statements of fact and inasmuch as a response is required, IGPM denies those statement and demands strict proof thereof.

20. IGPM incorporates its responses to the allegations contained in paragraphs 1 through 180 as its response to paragraph 181 of the Complaint.

21. IGPM incorporates its responses to the allegations contained in paragraphs 1 through 194 as its response to paragraph 195 of the Complaint.

22. IGPM incorporates its responses to the allegations contained in paragraphs 1 through 202 as its response to paragraph 203 of the Complaint.

23. IGPM admits the allegations contained in paragraph 211 of the Complaint that Drs. Mathis and O'Brien and Image Guided Pain Management, PC, through Drs. Mathis and O'Brien, had a duty to provide reasonable care and treatment to Mr. Wingate when he came to them for treatment and that they did provide Mr. Wingate reasonable care and treatment in the medical procedures performed, and IGPM is without knowledge to form a belief as to the truth of the allegations in paragraph 211 pertaining to Insight Health.

24. IGPM admits the allegations contained in paragraph 212 of the Complaint and states that Dr. O'Brien did obtain informed consent from Mr. Wingate for the procedure and described the nature of the procedure and known risks of the procedure and IGPM is without knowledge to form a belief as to the truth of the allegations in paragraph 212 pertaining to Insight Health.

25. IGPM incorporates its responses to the allegations contained in paragraphs 1 through 216 as its response to paragraph 217 of the Complaint.

26. IGPM incorporates its responses to the allegations contained in paragraphs 1 through 222 as its response to paragraph 223 of the Complaint.

27. IGPM admits the allegations contained in paragraph 224 of the Complaint because it did not know the drugs were being provided from a compounding pharmacy with the characteristics described in the Complaint and is without knowledge to form a belief as to the truth of the allegations contained in paragraph 224 as to Insight Health Corp.

28. IGPM denies all allegations of the Complaint not expressly addressed herein.

29. IGPM denies that they are guilty of any acts of negligence whatsoever in this case.

30. IGPM denies that any legal duty owed was violated.

31. IGPM denies that they are indebted to Plaintiff for the amount alleged in the Complaint or for any other sum whatsoever.

32. IGPM denies that Plaintiff's deceased was injured and damaged by the conduct as alleged and calls upon Plaintiff for strict proof of each and every item of alleged injury and damage.

33. IGPM reserves the right to amend this responsive pleading to assert affirmative defenses if the evidence gathered during discovery supports such affirmative defenses.

WHEREFORE, having fully responded to Plaintiff's Complaint, Defendants John M. Mathis, M.D.; Robert F. O'Brien, M.D.; and Image Guided Pain Management, P.C.

respectfully move this Court to enter judgment in their favor, to dismiss this action with prejudice, to award costs and attorneys' fees, and for such further relief as the Court deems appropriate.

### **CROSS-CLAIMS AGAINST INSIGHT HEALTH CORP.**

COME NOW, defendants John M. Mathis, M.D.; Robert F. O'Brien, M.D. and Image Guided Pain Management, P.C. (collectively "IGPM"), by counsel, pursuant to Rule 3:10 of the Supreme Court of Virginia, and state as follows for their cross-claims against Insight Health Corp.:

### **FACTUAL BACKGROUND**

1. On January 3, 2013, the Complaint in this matter was hand-delivered to counsel for IGPM with a request for waiver of service of process, and the waiver was granted.

2. Image Guided Pain Management, P.C. is a Virginia Corporation with its only two employees being Dr. John Mathis and Dr. Robert O'Brien.

3. The sole function and business purpose of IGPM is to provide radiology services through Drs. Mathis and O'Brien.

4. Insight Health Corp. ("Insight") is a Delaware corporation engaged in the business of providing equipment, management, administrative and other support services to medical practices.

5. On July 8, 2010, Image Guided Pain Management, P.C. entered into a management agreement ("Management Agreement") with Insight in which Insight agreed to provide the following services as an independent contractor:

- a. Day-to-day supervision, operation and sales/marketing management;

- b. Ordering necessary supplies and materials for the operation of the medical practice;
- c. Bookkeeping, budgeting, asset management, patient billings and record keeping, processing of accounts receivable, and managing and administering accounts payable;
- d. Providing all non-physician personnel deemed necessary by Insight for the proper and efficient operation of the medical practice.
- e. Managing and maintaining the leased premises where the medical practice is performed;
- f. Providing advertising and marketing services;
- g. Ensuring that the medical practice maintains all licenses, registrations and certificates required by federal, state and local law;
- h. Providing outpatient radiology information systems, including hardware and software necessary to manage the medical practice;
- i. Providing the necessary billing and collection system to accomplish routine functions of billing and collecting;
- j. Ensuring that all orders for imaging are documented in the patient's medical record;
- k. Complying with any third party payor requirements;
- l. Ensuring that all billing and collection practices shall be undertaken in compliance with all applicable federal and state laws and regulations; and
- m. Providing diagnostic imaging equipment as Insight deems appropriate, in its sole discretion, and contracting with parties for maintenance of such equipment.

6. Pursuant to the Management Agreement, title and ownership to all property, including information systems, is vested solely in Insight.

7. Insight agreed under the terms of the Management Agreement to perform its obligations in accordance with applicable federal and state statutes.

8. The Management Agreement also provides that Insight will indemnify and hold harmless IGPM for and will pay the amount of any damages, loss, liability, harm expenses, attorney fees, and costs of defense arising from or in connection with any breach by Insight of the Management Agreement or from or in connection with any negligent action, omission or willful misconduct by Insight.

9. Pursuant to the terms of the Management Agreement, Insight entered into contracts to obtain the drugs used by IGPM for epidural steroid injections, including contracts with New England Compounding Center ("NECC") for the purchase of methylprednisolone acetate.

10. Pursuant to the terms of the Management Agreement, Insight received from NECC the methylprednisolone acetate and managed the inventory of that drug to ensure that it was available for the operation of the medical practice, including for use in epidural steroid injections.

11. Pursuant to the terms of the Management Agreement, Insight provided and employed the personnel who ordered and purchased the methylprednisolone acetate from NECC and who managed the inventory of that drug to ensure that it was available for the operation of the medical practice.

12. Pursuant to the terms of the Management Agreement, Insight managed the accounts payable for the medical practice, including the documentation related to purchase of methylprednisolone acetate from NECC.

13. Pursuant to the terms of the Management Agreement, Insight managed the billing and accounts receivable for the medical practice, including the documentation related to sending bills to and receiving payments from patients and third party payors, including insurance companies, Medicare, and Medicaid.

14. Pursuant to the terms of the Management Agreement, Insight provided and employed the personnel who managed the accounts receivable for the medical practice, including the documentation related to sending bills to and receiving payments from patients and third party payors, including insurance companies, Medicare, and Medicaid.

15. Pursuant to the terms of the Management Agreement, Insight provided and managed the information management system for ordering supplies, and billing patients and third party payors.

16. Pursuant to the terms of the Management Agreement, Insight provided and employed the personnel who operated and managed the information management system for ordering supplies, and billing patients and third party payors.

17. Pursuant to the terms of the Management Agreement, Insight's employees entered the information into the Insight information management system for ordering supplies, including the information regarding the methylprednisolone acetate ordered from NECC.

18. Pursuant to the terms of the Management Agreement, Insight's employees entered the information into the Insight information management system for billing



patients and third party payors, including information about the drugs used for epidural steroid injections.

19. Pursuant to the terms of the Management Agreement, there was no employer/employee relationship between Insight and IGPM or between Insight and Dr. Mathis or Dr. O'Brien.

20. Pursuant to the terms of the Management Agreement, Insight and IGPM were independent contractors.

21. Insight and Insight's employees and agents did not provide to Dr. Mathis and Dr. O'Brien copies of the orders to NECC of the methylprednisolone acetate or copies of the Invoices from NECC for payment of the methylprednisolone acetate

22. Insight and Insight's employees and agents did not provide to Dr. Mathis and Dr. O'Brien copies of the bills or invoices sent to patients and third party payors, including insurance companies, Medicare, and Medicaid.

23. Dr. Mathis and Dr. O'Brien did not see the invoices and bills sent to patients and third party payors until after this lawsuit was filed.

24. Pursuant to the terms of the Management Agreement, IGPM was allowed to use the trade name "Insight Imaging" only for the purpose of identifying, advertising or promoting the medical practice and for no other purpose.

25. Insight should not be permitted to approbate and reprobate and avoid its obligations by asserting that the limited license to use its name "Insight Imaging" converted IGPM to Insight for all purposes of this litigation, which is not factually accurate under the Management Agreement and the facts in this case.

**Cross-Claim 1  
(Contractual Indemnity)**

26. IGPM incorporates and reasserts in this Cross-Claim 1 all allegations contained in Cross-Claim paragraphs 1 through 25 above.

27. The Management Agreement between Insight and IGPM requires Insight to indemnify and hold harmless IGPM for all claims asserted against IGPM arising from or in connection with Insight's negligence, omissions or willful misconduct related to Insight's performance of its obligations under the Management Agreement.

28. The Management Agreement between Insight and IGPM requires Insight to pay the amount of any damages, loss, liability, harm, expenses, attorney fees, and costs of defense arising from or in connection with Insight's breaches of the Management Agreement and in connection with Insight's negligence, omissions or willful neglect related to Insight's performance of its obligations under the Management Agreement.

29. The Management Agreement between Insight and IGPM requires Insight to indemnify and hold harmless IGPM for negligence, negligence *per se*, gross negligence, Consumer Protection Act, and fraud claims asserted against IGPM regarding Insight's purchasing of methylprednisolone acetate from NECC and supplying of the methylprednisolone acetate to the practice for use in epidural steroid injections.

30. The Management Agreement between Insight and IGPM requires Insight to indemnify and hold harmless IGPM for negligence, negligence *per se*, gross negligence, Consumer Protection Act, and fraud claims asserted against IGPM regarding Insight's coding, billing and invoicing practices.

31. On January 14, 2013, IGPM requested Insight to assume the defense of IGPM for this litigation, and Insight has refused to do so.

32. IGPM is entitled to indemnity from Insight pursuant to the terms of the Management Agreement.

WHEREFORE, John M. Mathis, M.D.; Robert F. O'Brien, M.D. and Image Guided Pain Management, P.C., by counsel, move this Court for judgment against Insight Health Corp. in the amount of any recovery Sharon G. Wingate, Executor of the Estate of Douglas Gray Wingate, deceased, is awarded or receives in settlement against John M. Mathis, M.D.; Robert F. O'Brien, M.D. and Image Guided Pain Management, P.C. and in the amounts of expenses, attorney fees, and costs of defense incurred for this litigation.

**Cross-Claim 2  
(Implied Indemnity)**

33. IGPM incorporates and reasserts in this Cross-Claim 2 all allegations contained in Cross-Claim paragraphs 1 through 32 above.

34. IGPM affirmatively states that it had no knowledge of the contents of the contracts between NECC and Insight and of the nature of the drugs Insight ordered from NECC, with the exception that the drugs were steroids purportedly suitable for epidural injections.

35. IGPM had no knowledge of the conditions of the manufacture or compounding of the drugs sold to Insight by NECC.

36. IGPM had no knowledge of the drug coding, billing and invoicing practices of Insight.

37. IGPM did not employ any of the individuals who ordered drugs from NECC, who paid for the drugs ordered from NECC, who coded the medications and who sent bills or invoices to the patients and third party payors.

38. In the alternative to the contractual indemnity claim above, IGPM is entitled to implied indemnity from Insight because IGPM was not negligent, did not violate the Consumer Protection Act and did not engage in fraud, as alleged.

WHEREFORE, John M. Mathis, M.D.; Robert F. O'Brien, M.D. and Image Guided Pain Management, P.C., by counsel, move this Court for judgment against Insight Health Corp. in the amount of any recovery Sharon G. Wingate, Executor of the Estate of Douglas Gray Wingate, deceased, is awarded or receives in settlement against John M. Mathis, M.D.; Robert F. O'Brien, M.D. and Image Guided Pain Management, P.C. and in the amounts of expenses, attorney fees, and costs of defense incurred for this litigation.

JOHN M. MATHIS, M.D.; ROBERT F.  
O'BRIEN, M.D.; and IMAGE GUIDED  
PAIN MANAGEMENT, P.C.

By:  \_\_\_\_\_  
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and exact copy of the foregoing was mailed this 4<sup>th</sup> day of February 2013 to the following counsel of record:

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A handwritten signature in black ink, appearing to read "Scott R. Ryan", is written over a horizontal line.